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Registration Standard for Pesticide Products Containing Coumaphos as the Active Ingredient

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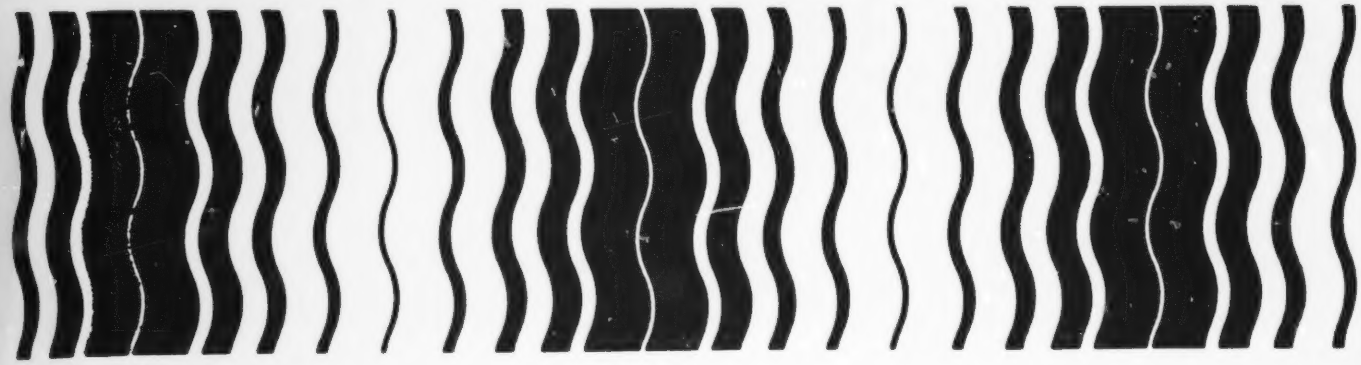
EPA

Registration Standard For Pesticide Products Containing COUMAPHOS As The Active Ingredient



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REGISTRATION STANDARD
(SECOND ROUND REVIEW)

FOR THE

REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING

COUMAPHOS

AS THE ACTIVE INGREDIENT

CAS REGISTRY NO. 56-72-4

OPP Chemical Code 036501

CASE NUMBER 0018

September, 1989

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D.C. 20460

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EPA Form 8570-27	Generic Data Exemption Statement

GLOSSARY OF TERMS AND ABBREVIATIONS

A	Acre
ADI	Acceptable Daily Intake. Also known as the Reference Dose or RfD.
a.i.	active ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CSF	Confidential Statement of Formula
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EPA	U.S. Environmental Protection Agency
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
LC_{50}	Median lethal concentration - a statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water or feed, e.g., mg/l or ppm.
LD_{50}	Median lethal dose - a statistically derived single dose than can be expected to cause death in 50% of the test animals, when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LEL	Lowest Effect Level
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted to the Agency.
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
OPP	Office of Pesticide Programs

PADI	Provisional Acceptable Daily Intake
ppm	parts per million
RfD	Reference Dose
TGAI	Technical Grade of the Active Ingredient
TMRC	Theoretical Maximal Residue Contribution

I. INTRODUCTION

This document is a revised Registration Standard for the subject chemical. In its original Standard, issued in August, 1981, the Agency assessed the available data supporting the registration of the pesticide to determine whether the pesticide met the "no unreasonable adverse effects" standard of FIFRA. The Agency concluded that additional data were necessary to fully evaluate the pesticide, and, as part of the issuance of the Standard, required that registrants supply those data. The Standard also set out labeling requirements that the Agency believed were necessary to ensure that products containing the pesticide were adequate to protect public health and the environment while the data were under development.

The Agency has reviewed the additional data submitted as of July 9, 1988 and has updated and revised its scientific and regulatory conclusions concerning the pesticide in light of expanded data requirements promulgated in 1984 as 40 CFR Part 158. The Registration Standard contains the Agency's updated scientific assessment[1] of this pesticide and its currently registered uses. As part of its review, the Agency has reassessed the tolerances for the pesticide and determined whether they are adequate. The tolerance reassessment is included in this Registration Standard. The Agency has also reviewed the labeling requirements for manufacturing-use and end-use products and is requiring label revisions.

This revised Registration Standard supersedes the original Registration Standard in its entirety.

This document contains the following sections:

- Section II describes the particular pesticide(s) covered by this Registration Standard, and gives a brief profile of its usage and composition. Regulatory history may be provided as well.
- Section III provides a summary of the current status of the data base. It sets out the Agency's scientific assessment of the health risks and environmental characteristics and effects of the chemical, which are updated from the original Registration Standard.

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[1] The scientific reviews and Compendium of Acceptable Uses are now available from the Field Operations Division (H7506C). Write to Office of Pesticides Program, EPA, Washington, DC 20460.

° Section IV explains the regulatory decisions and conclusions arising from the Agency's assessment, and the rationales for its decisions.

° Section V describes the labeling statements required for products containing the chemical. These are divided into statements for manufacturing-use products and statements for end-use products.

° Sections VI, VII, VIII, IX and X describe requirements for submission of generic data, product-specific data, and labeling.

° Appendix I contains a the data tables which describe data requirements for the chemical. The tables identify which requirements have been satisfied, as well as those for which gaps remain.

° Appendix II contains basic labeling information.

° Appendix III contains the bibliography. A Guide to Bibliography explains how to read and use the Bibliography.

° Appendix IV contains the necessary forms to respond to receipt of the Standard

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. Registrants must notify the Agency of any information, including interim or preliminary results of studies, if that information suggests possible adverse effects on man or the environment. This requirement is independent of the specific time requirements imposed by EPA for submission of completed studies called in by the Agency and continues as long as the products are registered under FIFRA.

II. CHEMICAL COVERED BY THIS STANDARD

A. DESCRIPTION OF CHEMICAL

The following chemical is covered by this Registration Standard:

Common Name: Coumaphos

Chemical Name: 0,0-diethyl 0-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphorothioate

Chemical Family: Organophosphate

Trade Names: Bay 21/199, Asuntol, Muscatox, Resitox, Baymix, Meldane, Co-Ral and Negashunt

Other Chemical Nomenclature: 0-3-chloro-4-methylcoumarin-7-yl 0,0-diethyl phosphorothioate; 3-chloro-7-diethoxyphosphino-thioyloxy-4-methylcoumarin; 0-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) 0,0-diethyl phosphorothioate (Chemical Abstracts, 9th Collective Index); 3,chloro-7-hydroxy-4-methylcoumarin 0-ester with 0,0-diethyl phosphorothioate (8th Collective Index); O,3-chloro-4-methyl-2-oxo-2H-chromen-7-yl 0-0-diethyl phosphorothioate; [0-(3-chloro-4-methyl-7-coumarinyl)] 0,0-diethyl phosphorothioate; 0,0-diethyl 0-(3-chloro-4-methyl-7-courmarinyl) phosphorothioate; phosphorothioic acid 0-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) 0,0-diethyl ester; 3-chloro-4-methylumbelliferone, 0-ester with 0,0-dietyl phosphorothioate; 0,0-diethyl 0-(3-chloro-4-methylumbelliferone thiophosphate.

CAS Registry Number: 56-72-4

EPA Pesticide Chemical Code (Shaughnessy Number): 036501

Empirical Formula: $C_{14}H_{16}ClO_5PS$

Molecular Weight: 362.8

Chemical/Physical Characteristics of the technical grade:

Color: grey to tan

Physical state: powder to granules

Odor: characteristic sulfur

Melting Point: 90 to 95 °C

Boiling Point: 20 °C at 10^{-7} mmHg

Solubility:

(at 20 °C):	g/100 mL at 20 C
acetone	23.82
methylene chloride	6.39
denatured alchohol	0.90
xylenes	0.90
hexanes	0.07
water insoluble at	0.002
octanol	0.13
odorless mineral spirits	0.09
diethyl phthalate	21.50

Vapor Pressure: 1×10^{-7} mmHg at 20 C

Density, Bulk Density, or
Specific Gravity: 30.06 lb/cu ft.

pH: 7.23 at 1 g/100 mL

Stability: hydrolyzes slowly under alkaline conditions; stable under normal storage conditions and use; incompatible with piperonyl butoxide

Storage Stability: Stable (<6% loss) in glass vials up to 8 weeks at -12 to 50 C, dry and at pH 4-10, at 83% moisture, exposed to aluminum, and stainless steel; stable exposed to sunlight for 4 days.

B. DATA CALL-INS ISSUED

There have been no 3(c)(2)(B) Data Call-In (DCI) Notices issued for coumaphos since the 1981 Standard.

C. USE PROFILE

Type of Pesticide:	Insecticide/acaricide
Year of Initial Registration:	1958
Registered Uses:	Indoor Use[2] on beef and dairy cattle; sheep; goats; horses; swine and swine bedding
Pests Controlled:	Face flies, horn flies, fly larvae, cattle grubs, ticks (including ear tick), lice, mites, screwworms, sheep keds and fleeceworms
Methods of Application:	Dust, spray, dip, pour-on, dust bags and backrubber oiler
Annual Usage:	264,000 to 525,600 lbs (1986 estimate)
Predominant Usage:	Predominate use is on beef cattle (98%). A relatively small amount is used on dairy cattle (<2%) and swine (<1%).
Mode of Activity:	Systemic and contact insecticide
Formulations:	Dust, wettable powder, pressurized liquid, liquid ready-to-use and emulsifiable concentrate
U.S. Manufacturer:	Bayvet, a division of Cutter Laboratories
Number of Registrations:	38 federally registered end-use products, 1 technical product and 1 formulation intermediate

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[2] Direct application to animals is considered an indoor use pattern.

III. AGENCY FINDINGS

A. CURRENT STATUS AND SUMMARY OF DATA BASE

The current status of the coumaphos data base and a summary of major science findings are provided below. The summarized points are presented in further detail in Sections IIIB through IIID.

1. Most of the toxicology testing requirements for coumaphos have been satisfied. This includes acute toxicity testing on registered end-use products. There were no toxicological concerns identified for this chemical (other than effects on cholinesterase inhibition). There are four outstanding data requirements: a structural chromosome aberration study, a dog chronic feeding study, a 21-day dermal toxicity study and a reproduction study. For each study, there is a different reason for why the Agency considers the requirement to be outstanding [Refer to Section IIIB]. Below is a summary of the major toxicological science findings for coumaphos:

   a. Technical coumaphos is highly acutely toxic by the oral and inhalation routes of exposure (Toxicity Category I and II, respectively) and moderately acutely toxic by the dermal route of exposure (Toxicity Category III) based on studies using rats, rabbits and guinea pigs. Technical coumaphos causes only mild eye and dermal irritation (Toxicity Category III and IV, respectively), and is nonsensitizing.

   b. End-use products containing coumaphos fall in a range of Toxicity Categories from I to III through the various exposure routes.

   c. Coumaphos does not produce organophosphate-type delayed neurotoxicity, based on acute neurotoxicity testing in hens.

   d. The oncogenic potential of coumaphos is satisfactorily defined. *In vitro* microbial studies for gene mutation and DNA damage coumaphos did not cause a mutagenic response, and when tested in the rat and mouse, there were no carcinogenic effects noted.

   e. Coumaphos is not a developmental toxicant, or teratogen based on findings in studies utilizing rats and rabbits.

   f. Results of a chronic feeding study using rats show that cholinesterase (plasma and erythrocyte) is the primary target of coumaphos. Decreased body weight gain is a secondary effect.

g. In a rat metabolism study, coumaphos was rapidly excreted. There were no dose-related changes in metabolism or evidence of activation/bioaccumulation.

2. The coumaphos data base for ecological effects testing is complete, with the exception of one special study. Based the on results of laboratory studies using birds, fish, and aquatic invertebrates, technical coumaphos is moderately acutely toxic to fish and very highly acutely toxic to birds and aquatic invertebrates. Coumaphos is moderately toxic to birds on a subacute (dietary) basis. A refined ecological risk assessment, performed for the livestock use, shows that aquatic invertebrates may be potentially exposed to hazardous levels of coumaphos resulting from washing-off of the material from the backs of newly treated cattle which have entered a body of water. Aquatic residue monitoring is required to assess the potential hazards. Due to the potential for avian exposure resulting from birds feeding on the backs of cattle and in cattle lots, Tier I avian field testing is required to assess possible adverse effects to birds resulting from the livestock treatment.

3. The environmental fate profile for coumaphos is adequately delineated for the registered use pattern, except for a groundwater assessment. Coumaphos is relatively immobile in aged sandy loam soil, based on findings in a column leaching study. There are no immediate concerns for groundwater contamination from non-point source application of coumaphos. However, the potential does exist for localized, point source contamination in animal treatment areas (particularly where animals are dipped), and as a result of associated disposal practices. Due to increased Agency sensitivity in the area of pesticides and groundwater contamination, four environmental fate studies are required so that the Agency can assess coumaphos' potential for point source contamination of groundwater.

4. Most of the residue chemistry conclusions drawn in the 1981 Standard have been reversed in this Standard. Residue chemistry data requirements were not imposed in the 1981 Standard. Since issuance of that Standard, the Agency has published residue chemistry guidelines (Pesticide Assessment Guidelines, Subdivision O, 1982, EPA-540/9-82-023) and other Federal Register (FR) Notices which provide a more stringent interpretation of the existing regulations. As a result of these new guidelines, data are now required in the area of animal metabolism, storage stability and method validation. No changes to coumaphos tolerances are indicated at this time.

5. The Agency is unable to totally assess the safety of current tolerances and establish an acceptable daily intake (ADI) value for coumaphos because of the absence of chronic toxicity studies (reproduction and dog chronic toxicity), and outstanding residue chemistry data. However, a preliminary dietary exposure analysis has been performed for coumaphos. Based on the results of this analysis, current coumaphos tolerances are considered to be adequate to protect the public health [Refer to discussion in Section IIID Tolerance Reassessment]. When the remaining data requirements have been fulfilled, the Agency will perform a final reassessment of coumaphos tolerances.

B. HEALTH EFFECTS ASSESSMENT

In the 1981 Standard, the Agency required submission of acute and subacute toxicity studies for technical and formulated products, a chronic feeding study, teratology and reproduction studies, mutagenicity studies and a metabolism study. Based on the Agency's review and evaluation of the current toxicity data base, all toxicity data requirements for registration of products containing coumaphos have been met, except for a 21-day dermal toxicity study, a non-rodent chronic toxicity study, a reproduction study, and a chromosome aberration study [reasons are explained below]. The toxicity profile of coumaphos, based on the results of acceptable studies, is provided below.

1. Acute Toxicity

Technical coumaphos is very highly acutely toxic, based on a reported oral LD_{50} of 17 mg/kg in female rats and greater than 240 mg/kg in male rats [Toxicity Category is I]. Technical coumaphos is moderately acutely toxic by the dermal route of exposure [Toxicity Category III] based on a reported LD_{50} value of greater than 2400 mg/kg in rabbits. In studies using rabbits, only mild irritation to the eyes [Toxicity Category III] and very minor irritation of the skin [Toxicity Category IV] was reported. There was no observable evidence of dermal sensitization reported in an acceptable dermal sensitization study using guinea pigs. In an acute inhalation study, the LC_{50} dose for a 1-hour exposure was determined to be 341 mg/m^3 in female rats and greater than 1080 mg/m^3 in male rats [Toxicity Category is II]. Coumaphos did not produce organophosphate-type delayed neurotoxicity when administered orally to hens protected with atropine at 1.5 times the acute LD_{50} in an acute delayed neurotoxicity study.

Thirty-six acute toxicity studies were submitted in support of registration of the end-use products. These studies were reviewed and found to be acceptable. Coumaphos end-use products range in toxicity from Toxicity Categories I through III. Appropriate precautionary statements, for each of the registered formulation types, are provided in Section V Required Labeling.

2. Subchronic Toxicity

Acceptable data are not available on the subchronic oral toxicity study of coumaphos in dogs. This study is not required since a chronic feeding study in dogs is required, and supercedes the need for a subchronic toxicity study. The previously accepted rat subchronic oral toxicity study is considered now to be inadequate, since a NOEL was not achieved in the study. A new study does not need to be performed, since there is an acceptable rat chronic toxicity study on file. In the 1981 Standard, the Agency asked for a 90-day dermal toxicity study to support coumaphos use on dogs and dog bedding. Label claims for use on dogs/dog bedding were dropped for the chemical. Hence, no subchronic dermal testing was performed for this chemical. The Agency is requiring a subchronic dermal toxicity study now, because application of coumaphos may result in repeated dermal exposure. This is especially true for the dust bag uses, when charging and recharging the bags. A subchronic neurotoxicity study is not required, since there was no evidence of neurotoxicity in the acute delayed neurotoxicity study.

3. Chronic Toxicity/Oncogenicity Testing

In a rat combined chronic feeding/oncogenicity study, groups of SPF Wistar rats (50/ sex/group) were administered 0, 1, 5, or 25 ppm (equivalent to 0, 0.07, 0.36, and 1.7 mg/kg/day) coumaphos in the diet for 2 years. Plasma ChE was inhibited in males and females in the 25 ppm group. Plasma ChE was also inhibited in females in the 5 ppm group. Erythrocyte ChE was inhibited in males and females in the 25 ppm group. Brain ChE was not inhibited in any of the groups. Females in the 25 ppm group exhibited decreased weight gain when compared to the controls. The NOEL (ChE) derived from this study is 1 ppm. The NOEL for other systemic effects is 5 ppm (based on a decrease in body weight gain in females). There was no evidence of oncogenicity noted in the study.

In a mouse oncogenicity study, groups of 50 mice/sex were administered 10 and 20 ppm (equivalent to 15 mg/kg and 30 mg/kg) of coumaphos in the diet for 103 weeks. A control group of 25 mice/sex was employed. No toxic/oncogenic effects were noted in this study.

A chronic feeding study in dogs is needed to complete the chronic effects testing data base for this chemical. This requirement was inadvertently omitted from the 1981 Standard.

4. Developmental Toxicity (Teratogenicity)

In studies utilizing rats and rabbits, coumaphos did not cause teratogenic or developmental effects. In the rat teratology study, groups of 50 female Charles River CD BS rats were administered 0, 1, 5, and 25 mg/kg on days 6 to 15 of gestation. Females in the 25 mg/kg group exhibited tremors. The maternal NOEL and LEL for this study were 5 and 25 mg/kg (based on the observation of cholinergic effects), respectively. The developmental NOEL was greater than 25 mg/kg (HDT). In the rabbit teratology study, groups of 17 inseminated rabbits were administered 0, 0.25, 2.0, and 18.0 mg/kg of coumaphos from days 7 to 19 of gestation. Several rabbits in the 18.0 mg/kg group exhibited signs indicative of ChE inhibition. The maternal NOEL and LEL for this study was 2.0 and 18.0 mg/kg, respectively. The developmental NOEL was greater than 18.0 mg/kg (HDT).

5. Reproduction

A reproduction study must be conducted. This study was originally required in the 1981 Standard. The Agency, in 1984, waived the requirement, agreeing with the registrant that a study was not needed since there were two acceptable teratology studies and a metabolism study. Since the purpose of a reproduction study is to provide information on the effects of the test substance on gonadal function, estrous cycles, mating behavior, conception, parturition, lactation, weaning, and the growth and development of the offspring, the Agency no longer believes a waiver is appropriate. Metabolism and teratology studies will not provide information on the majority of these toxicity endpoints. Therefore, a reproduction study must be conducted.

6. Mutagenicity

Technical coumaphos did not induce a mutagenic response in the two tests listed below.

a. Gene Mutation: A Salmonella/microsome study was conducted. Coumaphos was not mutagenic when tested at levels up to 12,500 ug/plate with and without metabolic activation in Salmonella typhimurium strains TA1535, TA1537, TA100, and TA98.

b. Direct DNA Damage and Repair: A test on Escherichia coli was conducted. Coumaphos was not mutagenic when tested at levels up to 5000 ug/plate with and without metabolic activation.

A previously accepted micronucleus study (00131682) is considered to be inadequate, since the test substance did not induce toxic effects in mice and only one dose level was tested. A new study must be conducted in accordance with the guidelines published in October 1982 (Subdivision F: Hazard Evaluation:Human and Domestic Animals, EPA-540/9-82-005).

7. Metabolism

Results of a rat metabolism study showed that coumaphos labelled on the leaving group (the most acidic group that is bonded to the phosphorus atom) was rapidly excreted as a conjugate in the urine. There were no dose-related changes in metabolism and no evidence of activation or bioaccumulation noted in this study.

8. Pesticide Incidents/Human Exposure

The Agency's nation-wide survey of hospitals (covering the period 1977-1982) contained only 1 out of 1,245 cases related to coumaphos (less than 0.1%). Exposure data are not required for this chemical. The Agency will evaluate the need for occupational and nonoccupational exposure data upon receipt and evaluation of the required toxicology data.

C. ENVIRONMENTAL CHARACTERISTICS AND EFFECTS

1. Ecological Effects

In the 1981 Standard, the Agency required submission of avian acute and subacute toxicity testing; and a fish acute LC_{50}. These studies have been submitted, and are adequate to support registration of products containing coumaphos. All ecological effects testing requirements for coumaphos have been met, with one exception [discussed below]. The ecological effects profile of coumaphos, based on the results of acceptable laboratory studies, is provided below.

Birds

The acute toxicity of technical coumaphos to birds ranges from highly to very highly toxic. On a subacute dietary basis, coumaphos is highly toxic to birds. Representative LD_{50} values are 29.4 mg/kg for mallard duck, 7.94 mg/kg for pheasant, and 2.4 mg/kg for bobwhite quail. Reported avian dietary LC_{50}s are 401 ppm for mallard and 82 ppm for bobwhite quail. Due to the potential for avian exposure resulting from birds feeding in cattle lots and on the backs of cattle, Tier I avian field testing is required to assess possible effects to birds resulting from direct treatment to livestock. Birds have been killed by feeding on the backs of cattle treated with other pesticides which were toxic to birds. In conjunction with this study, samples of hair and insects from the backs of cattle should be monitored for residues.

Aquatic Organisms

Technical coumaphos is moderately toxic to freshwater fish based on reported LC_{50}s for fish of 5.9 ppm in rainbow trout and 5.0 ppm in bluegill. Technical coumaphos is very highly toxic to aquatic invertebrates based on a reported

LC_{50} of 0.15 ppb in an amphipod, Gammarus lacustris.

There is a potential for exposure to aquatic organisms resulting from washing-off of the material from the backs of newly treated cattle which have entered a body of water, such as a pond or stream. Based on numerical calculations, application of coumaphos to a herd of 40 cattle at a rate of 0.0130 lb. ai/100 lb. of animal results in a concentration level of 15.9 ppb in 6 feet of water. This assumes that the cattle move into the water in a short period of time after application and that about 5% of the applied amount of the active ingredient is washed off. This concentration level exceeds the amphipod LC_{50} of 0.15 ppb. Based on this assessment, an acute hazard to aquatic invertebrates may exist. To evaluate the potential risk, a residue monitoring study is required.

A hazard to aquatic invertebrates may also exist as a result of improper disposal of spent dipping solution. Special disposal instructions (in compliance with RCRA) for used dip solutions resulting from the livestock dip use pattern are required as specified in Section V, Required Labeling.

Non-target Insects and Plants

Data requirements for non-target insect testing and non-target phytotoxicity testing are not applicable for coumaphos's indoor use pattern.

2. Environmental Fate

In the 1981 Standard, the Agency required submission of studies pertaining to aerobic soil metabolism, hydrolysis, photodegradation, volatility, adsorption/desorption, water dispersal, leaching, fish accumulation and a special test for composition and concentration in feces. After issuance of the 1981 Standard, Bayvet submitted waiver requests for many of the studies. The Agency agreed to waive requirements for volatility and composition/concentration in feces, since the poultry/poultry house claims were dropped. The Agency agreed to waive requirements for photodegradation and anaerobic soil metabolism, since it concluded that coumaphos would not reach soil or water on an area of several acres or more at detectable levels. The Agency agreed to waive the requirement for adsorption/desorption, since it determined that the potential for mobility could be determined from a column leaching study. Finally , the Agency agreed to waive the requirement for water dispersal, since were no aquatic uses for the chemical.

The Agency has reviewed the studies submitted in response to the 1981 Standard: hydrolysis (MRID 00159928), aerobic soil metabolism (MRID 40518701), fish accumulation (MRIDs 00115168 and 00150619) and leaching (MRID 00163806)[3].

The column leaching portion of the leaching study is acceptable and will support registration of products containing coumaphos. In this study, 30 day-old $[^{14}C]$coumaphos residues were relatively immobile in a column (24-cm length) of sandy loam soil. After leaching, the upper 6 cm of the soil column contained 97.93% of the recovered $[^{14}C]$ residues, the 6 to 12 cm depth contained 1.20%, the 12- to 24-cm depth contained 0.04%, and the leachate contained 0.40%. The radioactivity in the upper 6 cm of the sandy loam soil column was characterized as:14C]coumaphos, 95.8% of the recovered; chlorferone (3-chloro-4- methyl-7-hydroxycoumarin), 3.1%; the coumaphos oxygen analog (0,0-diethyl 0-3-chloro-4-methylcoumarin phosphate), 0.2%; and unidentified organosoluble [14C]residues, 0.9%. The material balance after leaching was 118.45% of the applied. Based on this data, coumaphos can be characterized as persistent, but immobile in sandy loam soils.

The other studies were found to be unacceptable due to design and reporting flaws. The fish accumulation study and aerobic soil metabolism study do not need to be repeated. The Agency no longer considers these studies necessary to support coumaphos's indoor use pattern. New hydrolysis and adsorption/desorption studies must be conducted to fully assess coumaphos' potential for contaminating groundwater.

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[3] **MRID 00115168** Lamb, D.W. 1985. Coumaphos ^{14}C accumulation and persistence of residues in bluegill. Report No. 71632. Unpublished study prepared by Mobay Chemical Corporation, Stilwell, KS, and submitted by Bayvet Division of Cutter Laboratories, Shawnee Mission, KS.

MRID 40518701 Olson, G., and L. Lawrence. 1987. Coumaphos--Aerobic soil metabolism study: PTRL Project No. 113. Unpublished study prepared by the Pharmacology and Toxicology Laboratory, Lexington, KY.

MRID 00150619 Waggoner, T. 1985. Inclusion of additional data to coumaphos-[carbon-12] accumulation and persistence of residues in blugill: Bayvet Report No. 71632. Unpublished study prepared by Bayvet Division of Miles Laboratories, Inc., Shawnee Mission, KS.

MRID 00159928 Waggoner, T. 1986a. Hydrolysis of [Carbon 14] coumaphos in sterile buffered aqueous solutions. Report No. 73320. Unpublished study prepared by the Pharmacology and Toxicology Laboratory, Lexington, KY.

MRID 00163806 Waggoner, T. 1986b. Leaching of aged residues of [carbon 14]-coumaphos in soil: Mobay Report No. 73431. Unpublished study prepared by the Pharmacology and Toxicology Laboratory, Lexington, KY.

There are no immediate concerns for groundwater contamination from non-point source application of coumaphos. However, the potential does exist for localized, point source contamination in animal treatment areas (particularly where animals are dipped), and as a result of associated disposal practices. In order to evaluate the potential for point source contamination, special studies are required: a photodegradation study in soil, a photodegradation study in water, an adsorption/desorption study, a hydrolysis study and a special retrospective field dissipation study. In the interim, special labeling requirements for disposal of spent dipping solutions are imposed (see under Section V, Required Labeling.

D. TOLERANCE REASSESSMENT

EPA has reviewed and evaluated the residue and toxicology data used in support of coumaphos tolerances to determine whether current tolerances are sufficient to cover the actual residues resulting from use, and to determine if tolerances are adequate to protect the public health, including that of sensitive subpopulations.

Most of the residue chemistry conclusions drawn in the 1981 Standard have been reversed. No residue chemistry data requirements were imposed in the 1981 Standard. Since issuance of that Standard, the Agency has published residue chemistry guidelines (Pesticide Assessment Guidelines, Subdivision O, 1982, EPA-540/9-82-023) and other FR Notices which provide a more stringent interpretation of the existing regulations. As a result of these new guidelines, data are now needed in the area of animal metabolism, storage stability and method validation.

The Agency's findings as a result of this evaluation are summarized below. The regulatory results of the Agency's review are set out in Section IV Regulatory Position and Rationale.

1. Tolerances Issued

U.S. tolerances are established for residues of the insecticide coumaphos, O,O-diethyl O-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphorothioate, and its oxygen analog, O,O-diethyl O-3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl-phosphate, in or on raw agricultural products as follows (40 CFR 180.189):

- 1 ppm in or on meat, fat, and meat byproducts of cattle, goats, hogs, horses, poultry[4], and sheep
- 0.5 ppm in milk fat (reflecting negligible residues in milk)
- 0.1 ppm in eggs[5]

The Food and Drug Administration (FDA) regulates the use of Coumaphos Crumbles (0.32% ai) as a top dressing on cattle feed (21 CFR 520.500) and coumaphos mixed with feed (21 CFR 558.185) administered at 0.00012-0.0002 lb ai/100 lb of body weight.

2. Residue Data

Below is a discussion of the residue chemistry data used in support of coumaphos tolerances.

a. Additional animal metabolism studies, conducted in ruminants, are required. In the 1981 Standard, the Agency concluded that the available data were sufficient to assure that coumaphos residues were adequately delineated based solely on data from metabolism studies in which poultry and ruminants were dermally treated with [^{32}P]coumaphos. These data are no longer considered acceptable because: (i) the fate of the ring moiety of coumaphos was not determined; (ii) many metabolites were not conclusively identified or adequately quantitated; (iii) ^{32}P-activity was not adequately accounted for in all tissues; and (iv) many studies are from open literature thus raw data are unavailable. Although the available data provide some information regarding the identities and distributions of ^{32}P-residues in meat and milk, metabolism studies using ring-labeled [^{14}C]coumaphos are required to adequately characterize the terminal residues. The molecular structures of coumaphos and its metabolites identified in animals treated with [^{32}P] coumaphos are depicted in Table 1.

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[4] There are no longer any federally registered uses for poultry/poultry houses. Therefore, the Agency intends to revoke the tolerances for poultry and eggs.

Table 1. Coumaphos and Its Metabolites in Animal

Chemical Name	Substrate	Common Name
I. O,O-diethyl O-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphorothioate	Milk Cattle fat, liver, kidney Swine fat Sheep fat Cattle feces Egg yolk (putative) Poultry feces Poultry skin	Coumaphos
II. O,O-diethyl O-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphate	Milk Ruminant tissues (unspecified) Egg yolk (putative) Poultry feces Cattle feces	Coumaphos oxygen analog
III. O-ethyl O-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphorothioate	Milk Ruminant urine	De-ethylated coumaphos

Table 1. Coumaphos and Its Metabolites in Animal

	Chemical Name	Substrate	Common Name
IV.	O-ethyl O-(3-chloro-4-methyl-2-oxo-2H-1-benezopyran-7-yl) phosphate	Milk Ruminant urine	De-ethylated coumaphos oxygen analog
V.	3-chloro-4-methyl-7-hydroxycoumarin	Rabbit feces Cattle tissues[1] (putative)	Chlorferrone, Chlorferone, Chlorferron
VI.	O,O-diethyl-O-(4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphorothioate	Rabbit feces Cattle tissues[1] (putative)	Potasan
VII.	diethyl phosphorothionic acid	Milk Poultry feces Cattle urine	Diethyl phosphorothionic acid

Table 1. Coumaphos and Its Metabolites in Animal

	Chemical Name	Substrate	Common Name
VIII.	diethyl phosphoric acid	Milk Poultry feces Cattle urine	Diethyl phosphoric acid
IX.	monoethyl phosphorothioic acid	(putative)[1]	
X.	monoethyl phosphoric acid	Cattle, goat urine (putative) Poultry feces	Monoethyl phosphoric acid
XI.	phosphoric acid	Milk Cattle urine, feces	Phosphoric acid
XII.	phosphorothioic acid	(putative)[1]	

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[1] The 1981 Standard identified chlorferron and potasan as putative metabolites of coumaphos, and did not require additional methods for the enforcement of the tolerances of coumaphos and it oxygen analog. However, since the nature of the residues in animals is not understood, the adequacy of the available analytical methods can not be ascertained. Methods to be used for data collection and tolerance enforcement will be determined upon receipt of the requested metabolism data.

b. Additional storage stability data are required. Although it was concluded in the 1981 Standard that adequate storage stability data were available, these data reflected storage of the 25% WP product, not samples of commodities bearing coumaphos residues. No data reflecting the storage of meat or tissues were submitted. Data must be submitted which conforms to the Pesticide Assessment Guidelines, Subdivision O.

c. Data are required concerning recovery of coumaphos and the coumaphos oxygen analog by certain of the Multiresidue Protocols I-IV, as per FR 51(187)34249.

d. The adequacy of the available data pertaining to residues of coumaphos and its oxygen analog in animal commodities cannot be ascertained, since the qualitative nature of the residue in animals is not adequately understood. Upon receipt of the requested animal metabolism data, the adequacy of the established tolerances will be determined. If these studies reveal the existence of additional residues of toxicological concern, additional data may be required.

e. The tolerance established by the Canadian government is 0.5 ppm in meat, meat byproducts and fat of cattle, goats, horses, hogs, poultry, and sheep. This is lower than the U.S. tolerance due to different methods of setting tolerances. The Canadian tolerance reflects expected residues that are statistically determined percentages of the maximum residues, rather than the maximum residues used in setting U.S. tolerances. Temporary Codex Maximum Residue Levels of 1 ppm in poultry and fat of meat of cattle, 0.5 ppm in fat of meat of sheep, pigs, goats, milk, and milk products, and 0.05 ppm in eggs are proposed to be revoked due to a lack of supporting data.

f. Regulatory Incidents: No finding of coumaphos were reported in 1 sample of meat byproducts; 12 samples of milk, cream, and cheese; 1 sample of poultry byproduct; 2 samples of eggs; 8 samples of noodles (likely to contain eggs); or in numerous samples of plant commodities collected in FDA domestic and import surveillance from 1986 to 1988.

3. Acute and Chronic Dietary Exposure Analysis

The Provisional Acceptable Daily Intake (PADI) for coumaphos is 0.0007 mg/kg/day and is based on the 2-year rat feeding/oncogenicity study NOEL of 0.07 mg/kg/day (based on plasma cholinesterase inhibition in females) and uncertainty factor of 100.

A preliminary dietary exposure analysis, performed for the registered uses of coumaphos assuming that 100% of the commodities contained tolerance level residues, resulted in exposure estimates that exceeded the reference dose. Consequently, anticipated residue data were developed for meat and milk. Simple calculations of average and "upper-bound" anticipated residue levels were not possible due to limitations in the data base (e.g. residue data dating to pre-1968, many exaggerated rate studies, dissimilarity in measuring residue levels from study to study, and lack of information regarding typical rates of application, application rates and preslaughter intervals). Because of these limitations, a residue decline analysis was performed for each available residue study to calculate average and "upper-bound" 95% confidence limit values between zero and 14 days after treatment. The highest average values between zero and 14 days for each study were used to calculate an average anticipated residue. The highest 95% confidence limit (or highest residue level found) between zero and 14 days was determined for each study, and the highest of these from all studies was used for the "upper-bound" anticipated residue. High values which appeared to be "outliers" were excluded from the data sets if the values appeared unrealistically high because the data sets were small or because the value was obtained by extrapolation to higher or lower PHIs for which residue data were not available.

The calculated values reflect those expected from chronic (based on average residues) and acute (based on highest residue found or 95% confidence limit) exposure.

The analysis did not take into account reduction in residues from cooking or percent of animal treated data, since data in either area were unavailable. The Agency considered the total toxic residue to include coumaphos and its oxygen analogue as described in the tolerance expression, since the metabolism of coumaphos is not considered adequately understood. Due to a wide range of residues found in beef fat, residue data were weighted by the approximate percent of each type of application made to beef cattle based on the best available data (approximately 60% dust and 40% spray or dip) in calculating the "upper-bound" value.

Table 2: Anticipated Residues for Coumaphos for Use in Calculating Chronic and Acute Exposure

Commodity	Anticipated Residue(ppm)	
	Average	Upper Bound
Beef (and horse), lean meat without removable fat	0.03	0.05
, fat	0.15	0.40
, liver (and meat by-products)	0.10	0.10
, kidney	0.04	0.04
Goat, lean meat without removable fat	0.04	0.20
, fat	0.50	1.0
, liver (and meat by-products)	0.03	0.03
, kidney	0.02	0.03
Hog, lean meat	0.03	0.20
, fat	0.06	0.60
, liver (and meat by-products)	0.02	0.02
, kidney	0.02	0.02
Sheep, lean meat without removable fat	0.05	0.25
, fat	0.50	1.0
, liver (and meat by-products)	0.03	0.08
, kidney	0.04	0.09
Milk	0.006	0.02

Chronic Exposure Analysis

The chronic dietary exposure analysis was performed using average anticipated residue values. The Anticipated Residue Contribution (ARC) for the United States population is calculated to be 0.000127 mg/kg/day, occupying 18.2% of the PADI. The two highest calculated exposures for the population subgroups are children 1 to 6 years of age [ARC occupies 33.6% of the PADI] and children 7 to 12 years of age [ARC occupies 25.6% of the PADI].

Acute Exposure Analysis

The acute dietary exposure analysis was performed using "upper-bound" anticipated residues. The analysis was used to estimate the distribution of single-day exposures for the overall U.S. population average and certain population subgroups (male, female, children and infants). The acute dietary exposure to coumaphos is compared to the NOEL for ChE inhibition of 5 mg/kg body weight from an acute toxicity rat study [acute toxicity endpoint = inhibition of cholinesterase; LEL = 5 mg/kg body weight]. The margin of safety (MOS) for acute exposure is calculated as the ratio of the NOEL to the estimated exposure[5]. Results of these calculations indicate that acute exposure to coumaphos is not expected to result in an MOS less than 500 for any TAS population group.

The Agency is unable to totally assess the safety of current tolerances and establish an acceptable daily intake (ADI) value for coumaphos because of the absence of chronic toxicity studies (reproduction and dog chronic toxicity), and outstanding data in the area of animal metabolism, method validation and storage stability. When the required data have been submitted and evaluated, the Agency will perform a final reassessment of coumaphos tolerances.

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[5] For example, the estimated MOS for the average U.S. consumer is calculated as:

MOS = NOEL / EXPOSURE (ARC)
= (5 mg/kg) / 0.000798 mg/kg body weight
= 6300 (Approximately)

IV. REGULATORY POSITION AND RATIONALE

A. SUMMARY OF REGULATORY POSITIONS AND RATIONALES

Based on a review and evaluation of all available data and other relevant information on coumaphos, the Agency has made the following determinations:

1. The Agency is not initiating a Special Review for this chemical.

Rationale: No Special Review concerns were identified for this chemical by the Agency during its review of the current data base.

2. The Agency is classifying coumaphos 11.6% EC and 42% flowable concentrate end-use products as restricted use due to acute oral hazards.

Rationale: Section 3(d)(1)(c) of FIFRA provides that some or all uses of a pesticide will be classified for restricted use if the Administrator determines that without such restriction the pesticide "may generally cause unreasonable adverse effects in man or the environment." Because of the high acute oral toxicity of the 11.6% EC and 42% flowable concentrate formulations, the Agency is classifying these products as restricted-use.

3. The Agency will approve new food/feed tolerances for coumaphos on a case-by-case basis.

Rationale: Based on the results of a preliminary dietary exposure analysis, the Agency believes that current coumaphos tolerances are adequate to protect the public health. The Anticipated Residue Contribution (ARC) represents only 18.2% of the PADI for the U.S population average. However, data are lacking in the area of animal metabolism, method validation, storage stability, and chronic toxicology (dog chronic toxicity and reproduction). Therefore, if an applicant submits a petition for a new food or feed use, the Agency will consider the request on a case-by-case basis. Such evaluation will include the incremental contribution to the anticipated residues.

4. Environmental fate testing is required to evaluate coumaphos' potential for impacting groundwater or surface water resulting from point source application.

Rationale: There are no immediate concerns for groundwater contamination from non-point source application of coumaphos. However, the potential does exist for localized, point source contamination in animal treatment areas (particularly where animals are dipped), and as a result of associated disposal practices. Four environmental fate studies (adsorption/desorption, retrospective field dissipation study, hydrolysis, and photodegradation) are required to assess coumaphos's potential for contaminating groundwater.

5. Labels bearing directions for use on goats and sheep must be amended to specify a preslaughter interval (PSI) of 3 days.

Rationale The 15 day preslaughter interval established for goats and sheep is considered inappropriate. Agency policy is that a PSI greater than 3 days is not practical or enforceable, because livestock can be transferred quickly from an owner who has applied the pesticide to one who is not aware of the animal's treatment history.

6. Coumaphos product labels must bear revised and updated labeling that accurately reflects hazards to nontarget organisms. Refer to Section V for the wording of these statements.

Rationale: Label statements are required since laboratory data show that coumaphos is highly to very highly toxic to birds, very highly toxic to aquatic invertebrates and moderately toxic to fish.

7. A special aquatic residue monitoring study is required.

Rationale: Results of laboratory testing, in conjunction with theoretical monitoring, indicate that aquatic invertebrates may be potentially exposed to hazardous levels of coumaphos as a result of washing-off of the material from the backs of newly treated cattle which have entered a body of water, such as a pond or stream. A residue monitoring study is required in order that the Agency may assess the risk to aquatic invertebrates resulting from direct animal treatment.

8. A special avian Level I field study is required.

Rationale: Results of laboratory testing indicate that this chemical is very highly acutely toxic to birds and moderately toxic on a subacute (dietary) basis. Due to the potential for avian exposure resulting from birds feeding in cattle lots and on the backs of cattle, Tier I avian field testing is required to assess possible effects to birds resulting from direct treatment to livestock.

9. The Agency is requiring protective clothing statements for coumaphos products falling in Toxicity Category I and II.

Rationale: Coumaphos is a cholinesterase inhibitor. Protective clothing is necessary to reduce exposure to individuals (including dip tank workers) who mix, load, and/or apply coumaphos products.

10. The Agency will revoke the poultry and egg tolerances.

Rationale: Coumaphos is no longer federally registered for use on poultry or in poultry houses. Therefore, the Agency will revoke the tolerances for poultry and eggs.

11. End-use product labels must specify a maximum single application rate expressed in terms of amount of active ingredient per animal, a maximum seasonal application rate or number of applications permitted per season, and a minimum interval between applications.

Rationale: Some of the end-use product labels do not contain restrictions on use as described above. For those products which do not contain directions for use specifying a maximum single application rate expressed in terms of (1) amount of active ingredient per animal; (2) a maximum seasonal application rate or number of applications permitted per season; and (3) a minimum interval between applications, revised labeling must be submitted.

12. There are no inconsistencies between the U.S. tolerances and Codex Maximum Residue Levels (MRLs).

Rationale: Temporary Codex MRLs established for coumaphos residues in animal products are proposed to be revoked due to a lack of supporting data. Therefore, no questions of compatibility exist with respect to the U.S. tolerance and Codex MRLs.

13. The Agency has identified certain data that will receive priority review when submitted to the Agency.

Rationale: Certain data are essential to the Agency's assessment of this pesticide and its uses and/or may trigger the need for further studies which should be initiated as soon as possible. The following studies have been identified to receive priority review as soon as they are received by the Agency:

Fish and Wildlife

70-1 Aquatic Residue Monitoring Data

71-5 Simulated or Actual Field Testing With Mammals and Birds

Environmental Fate

158.75 Special Retrospective Field Dissipation Study
161-1 Hydrolysis
161-2 Photodegradation Study in Water
161-3 Photodegradatiuon Study in Soil
163-1 Adsorption/Desorption Study

13. While data gaps are being filled, currently registered products containing coumaphos may be sold, distributed, formulated, and used, subject to the terms and conditions specified in this Standard. However, significant new uses will not be registered. Registrants must provide or agree to develop additional data, as specified in the Data Appendices, in order to maintain existing registrations.

Rationale: Even when authorized under FIFRA sections 3(c)(2)(B) and 3(c)(7) the Agency may elect not to cancel or withhold registration even though data are missing or are inadequate. Issuance of this Standard provides a mechanism for identifying data needs. These data will be reviewed and evaluated, after which the Agency will determine if additional regulatory actions are necessary. The Agency has elected not to consider registration of any significant new food uses while data gaps are being filled and data evaluated.

V. REQUIRED LABELING STATEMENTS AND COMPLIANCE DATES

All products must bear appropriate labeling as specified in 40 CFR 156.10 and below.

Pesticide products containing this pesticide as an active ingredient may not be released for shipment by the registrant after November, 1990 unless the product bears amended labeling that complies with the requirements of FIFRA, as set out in this Registration Standard.

Pesticide products containing this pesticide as an active ingredient may not be distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received (and having been so received) delivered or offered to be delivered by any person after November, 1991 unless that product bears amended labeling that complies with the requirements of this Standard.

A. MANUFACTURING USE PRODUCTS

1. The ingredient statement for MPs must declare the

active ingredient as:

"O,O-diethyl O-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphorothioate......"

2. Labels for MPs must bear the following identifying phrase directly beneath the product name:

"An insecticide for formulating use only."

3. In the directions for use, the following statement must appear:

"Formulators using this product are responsible for obtaining EPA registration of their formulated product."

4. In the directions for use, the following statement regarding acceptable use patterns must appear:

"For formulation into end-use insecticide products intended only for (list acceptable sites)."[6]

5. If detailed instructions for formulating are not provided on the label, the following statement must appear:

"Refer to attached Technical Bulletin for formulating and other information."

6. The following statements are required to appear under the "Environmental Hazards" heading:

"This pesticide is toxic to birds, fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in a NPDES Permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA."

B. END USE PRODUCTS

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[6] The Use Index (EPA Compendium of Acceptable Uses) (for availability see Section I) lists all federally-registered uses of coumaphos, as well as approved maximum application rates and frequencies. No use may be included on the label where the registrant fails to agree to comply with the data requirements for that use pattern.

1. The ingredient statement for EPs must declare the active ingredient as:

"O,O-diethyl O-(3-chloro-4-methyl-2-oxo-
2H-1-benzopyran-7-yl) phosphorothioate......"

2. The following statements are required to appear under the "Environmental Hazards" heading for all EP products:

"This pesticide is toxic to birds, fish and aquatic invertebrates. Do not contaminate water when disposing of equipment washwater or rinsate."

3. Coumaphos 11.6% EC and 42% flowable concentrate formulations must bear the following restricted-use statement:

"RESTRICTED USE CLASSIFICATION
Due to acute oral hazards
For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

4. All products intended for direct animal treatment to sheep and goats must bear the following statement:

"Do not treat within three days of slaughtering."

5. All EP products in Toxicity Category I or II (except those formulated as aerosol products) must bear the following worker protection clothing statements:

"USE ONLY WHEN WEARING THE FOLLOWING PROTECTIVE CLOTHING AND EQUIPMENT DURING MIXING/LOADING, APPLICATION, REPAIR AND CLEANING OF MIXING, LOADING, AND APPLICATION EQUIPMENT, DISPOSAL OF THE PESTICIDE; long-sleeved shirt and long-legged pants; chemical resistant gloves; chemical resistant shoes (or chemical resistant shoe covers or chemical resistant boots). In addition, mixers/loaders **and dip tank workers** must wear a chemical resistant apron and face shield or goggles, and a NIOSH/MSHA approved respiratory protection device."

6. Labels for all EP products (except those bearing direction for livestock dip treatment and those formulated as aerosol products) which are assigned to Toxicity Category I on the basis of oral or dermal toxicity, skin or eye irritation potential, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statements in accordance with PR Notices 83-3 and 84-1.

"Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label directions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

7. Labels for products formulated as aerosols may bear the following pesticide disposal:

"Replace cap and discard containers in trash. Do not incinerate or puncture."

8. All products allowing for use as a livestock dip treatment must contain the following disposal statements:

"Used dip solutions must be disposed of in accordance with the Resource Conservation and Recovery Act (RCRA). If the applicator generates more than 1000 kg of used dip solution per month or more than 1000 kg used dip solution in combination with other hazardous waste, the material must be treated as a hazardous waste subject to subpart C of RCRA. Any user who wishes to treat, store or dispose of hazardous waste must obtain a permit to serve as a hazardous waste facility pursuant to RCRA."

9. Each end-use product label must be revised to reflect the appropriate signal word and set of precautionary statements assigned to it based on the results of acceptable acute toxicity testing:

11.6% EC

"PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
DANGER --POISON (skull and crossbones)

Fatal if swallowed. May be fatal if inhaled. Do not breathe vapors or spray mist. Avoid contact with skin, clothing or eyes. Wash thoroughly with soap and warm water after handling. Wash contaminated clothing with soap and hot water before use."

3% Spray

"PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS & DOMESTIC ANIMALS
DANGER

Corrosive. Can cause irreversible eye damage. Do not get in eyes. Wear safety glasses or goggles.
Harmful if swallowed, inhaled or absorbed through skin. Avoid breathing spray mist. Avoid contact with skin and clothing."

4% Pour-On

"PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
WARNING

May be fatal if swallowed or inhaled. Do not breathe vapors or spray mist. Avoid contact with skin, clothing or eyes. Causes moderate eye irritation."

25% WP

"PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
WARNING

May be fatal if swallowed or inhaled. Do not breathe dust or spray mist. Causes moderate eye irritation. Avoid contact with eyes, skin, or clothing."

42% Flowable

"PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
DANGER -- POISON (skull and crossbones)

Fatal if swallowed or absorbed through the skin. Do not breathe spray mist. Do not get in eyes, on skin, or on clothing. Wash thoroughly with soap and warm water after handling. Wash contaminated clothing with soap and hot water before use."

1% ,0.5% D

"PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION

Harmful if swallowed, inhaled, or absorbed through skin. Avoid breathing dusts. Avoid contact with eyes, skin, and clothing."

5% D

"PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
WARNING

May be fatal if swallowed, inhaled or absorbed through the skin. Avoid contact with skin or eyes. Avoid breathing dusts."

10. For the liquid formulations, the following STATEMENT OF PRACTICAL TREATMENT is required:.

"STATEMENT OF PRACTICAL TREATMENT

If swallowed - Call a physician or Poison Control Center immediately. If possible, vomiting should be induced under medical supervision. Drink one or two glasses of water and induce vomiting by touching the back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

If inhaled - Remove victim to fresh air. Apply artificial respiration if indicated. Get medical attention if victim displays signs of poisoning.

If on skin - Remove contaminated clothing and wash affected areas with soap and water.

If in eyes - Flush eyes with plenty of water. Call a physician immediately."

11. For the dust and wettable powder formulations, the following STATEMENT OF PRACTICAL TREATMENT is required:

"STATEMENT OF PRACTICAL TREATMENT

If swallowed - Call a physician or Poison Control Center immediately. Drink one or two glasses of water and induce vomiting by touching the back of throat with finger. Repeat until vomit fluid is clear. Do not induce vomiting or give anything by mouth to an unconscious person.

If inhaled - Remove victim to fresh air. Apply artificial respiration if indicated. Get medical attention if victim displays signs of poisoning.

If on skin - Remove contaminated clothing and wash affected areas with soap and water.

If in eyes - Flush eyes with plenty of water. Call a physician immediately."

11. Revised labeling must be submitted for those products which do not contain directions for use specifying a maximum single application rate expressed in terms of: (1) amount of active ingredient per animal; (2) a maximum seasonal application rate or number of applications permitted per season; and (3) a minimum interval between applications, revised labeling must be submitted.

VI. PRODUCTS SUBJECT TO THIS STANDARD

All products containing the pesticide identified in Section II.A. are subject to certain requirements for data submittal or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing use product or an end use product.

All products are subject to this Registration Standard as follows:

A. Manufacturing use products containing this pesticide as the sole active ingredient or in combination with another active ingredient(s) are subject to:

    1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.

    2. The data requirements listed in Tables A and B .

    3. The labeling requirements specified for manufacturing use products in Section V.

    4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

C. End use products containing this pesticide as the sole active ingredient or in combination with another active ingredient(s)are subject to:

    1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end use product.

    2. If eligible for the generic data exemption , the data requirements listed in Table C.

    3. If not eligible for the generic data exemption, the data requirements listed in Table A and the data requirements listed in Table C.

    4. The labeling requirements specified for end use products in Section V.

VII. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient.[3]

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and 40 CFR 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

If you are granted a generic data exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrants who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this data requirements notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your product(s) and their product(s) unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

If you are not now eligible for a generic data exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Generic Data Exemption Statement.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submittal or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirement

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an

agreement exists, or (3) a written statement by the person who will be submitting the data that you may rely upon its submittal. The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

If you and other registrants together are generating or submitting requested data as a task force or consortium, a representative of the group should request a Joint Data Submitter Number, as part of your 90-day response. The request must include the following information:

a. A list of the members of the consortium;
b. The name and address of the designated representative of the consortium, with whom EPA will correspond concerning the data;
c. Identity of the Registration Standard containing the data requirement;
d. A list of the products affected (from all members of the consortium); and
e. Identification of the specific data that the consortium will be generating or submitting.

The Agency will assign a number to the consortium, which should be used on all data submittal by the consortium.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

1. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

2. Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

> [Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec. 3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA sec. 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data.

In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice in a timely manner. If the other registrant fails to develop the data or for some other reason would be subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the time-frames for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data. The Agency will respond in writing to your request for a waiver.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are

needed.

E. Registrant Requests Regarding Data Requirements and and Agency Responses

All requests for modification of data requirements (inapplicability, waiver), approval of protocols or protocol changes, or time extensions must be submitted in writing. The original requirement remains in effect unless the Agency has notified you in writing that it has agreed to a change in the requirement. While being considered by the Agency, such requests for changes in the requirements do not alter the original requirements or extend the time allowed for meeting the requirement.

F. Test Protocols and Standards

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines, unless other protocol or standards are approved for use by the Agency in writing. All testing must be conducted in accordance with applicable Good Laboratory Practices regulations in 40 CFR Part 160.

The Pesticide Assessment Guidelines, which are referenced in the Data Tables, are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (Part 158.70). Please note, however, that certain OECD standards (such as test duration, selection of test species, and degradate identification which are environmental fate requirements) are less restrictive than those in the EPA Assessment Guidelines listed above. When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of Part 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accord with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue, N.W., Washington, D.C. 20006.

G. Procedures for requesting a change in test protocol

If you will generate the required data and plan to use test procedures which deviate from EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submittal of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols. The Agency will respond in writing to your request for protocol approval or change.

H. Procedures for requesting extensions of time

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time.

EPA will view failure to request an extension before the data submittal response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome. The Agency will respond in writing to any requests for extension of time.

I. Data Format and Reporting Requirements

All data submitted in response to this Notice must comply with EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR Notice 86-5 (issued July 29, 1986). All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submittal requirement.

J. Existing stocks provision upon suspension or cancellation

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision for the registrant is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VIII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. If you have an end use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section VII. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are: 1) submit data; or 2) cancellation of registration.

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

IX. REQUIREMENT FOR SUBMITTAL OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 156.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling language specific to products containing this pesticide is specified in Section IV.D of this Registration Standard. Responses to this Registration Standard must include draft labeling for Agency review.

Labeling must be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. Draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

If you fail to submit revised labeling as required, which complies with 40 CFR 156.10 and the specific instructions in Section V, EPA may seek to cancel the registration of your product under FIFRA sec. 6.

X. INSTRUCTIONS FOR SUBMITTAL

All submittal in response to this Registration Standard must be sent to the following address:

Document Processing Desk RS-CASE 0018
Office of Pesticide Programs H7504C
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

Attn: Coumaphos Registration Standard

A. All Manufacturing Use Products (MUPs) - Sole Active Ingredient and Multiple Active Ingredient

1. Within 90 days from receipt of this document, you must submit for each product subject to this Registration Standard:

   a. Generic Data Exemption Statement (EPA Form 8580-3), if applicable, or the "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.

   b. Confidential Statement of Formula (EPA Form 8570-4).

   c. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

2. Within 1 Year from receipt of this document you must submit:

   a. Application for Pesticide Registration (EPA Form 8570-1).

   b. Three copies of any required product-specific data (See Table B).

   c. Five copies of draft labeling, including the container label and any associated supplemental labeling.

   d. Product Specific Data Report (EPA Form 8580-4).

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

B. End Use Products Containing the Subject Pesticide as Sole Active Ingredient, or in Combination With Another Ingredient(s).

1. Within 90 days from receipt of this document, you must submit:

   a. Generic data exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

   b. Confidential Statement of Formula (EPA Form 8570-4).

2. Within i Year from receipt of this document you must submit:

   a. Three copies of any product-specific data, if required by Table C.

   b. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

   c. Five copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

I. DATA APPENDICES

GUIDE TO TABLES

Tables A, B, and C contain listings of data requirements for the pesticides covered by this Registration Standard.

Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

Table B contains product-specific data requirements that apply only to a manufacturing use product.

Table C contains product-specific data requirements that apply only to an end use product.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Prot Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure Active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food

F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

> YES - EPA has data in its files that completely satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.
>
> PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.
>
> NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column e indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not

have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column t requires that data be submitted, this column indicates when the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

Table A
Generic Data Requirements for Coumaphos

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
Part 158, Subpart C - Product Chemistry					
Product Identity and Composition					
61-2 - Beginning Materials and Production Process	TGAI	Partially	00110596	Yes[1]	1 Year
61-3 - Formation of Impurities	TGAI	Partially	00110596	Yes[2]	1 Year
Analysis and Certification of Product Ingredients					
62-1 - Preliminary Analysis	TGAI	Partially	00110596	Yes[3]	2 Years
Physical and Chemical Characteristics					
63-2 - Color	TGAI	Yes	00110596	No	
63-3 - Physical State	TGAI	Yes	00110596,00021999	No	
63-4 - Odor	TGAI	Yes	00110596	No	
63-5 - Melting Point	TGAI	Yes	00110596,00021999	No	
63-6 - Boiling Point	TGAI	Yes	00021981	No	
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	Yes	00110596	No	
63-8 - Solubility	TGAI or PAI	Yes	00110596	No	

Table A
Generic Data Requirements for Coumaphos (cont'd)

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
Part 158, Subpart C - Product Chemistry (cont'd)					
Physical and Chemical Characteristics (cont'd)					
63-9 - Vapor Pressure	TGAI or PAI	Yes	00005193	No	
63-10 - Dissociation Constant	TGAI or PAI	No		Yes[4]	1 Year
63-11 - Octanol/Water Partitioning Coefficient	PAI	No		Yes[4,5]	1 Year
63-12 - pH	TGAI	Yes	00110596	No	
63-13 - Stability	TGAI	Partially	00021981,00141225	Yes[4]	1 Year
Other Requirements					
64-1 - Submittal of Samples	TGAI	No		No[6]	

Table A
Generic Data Requirements for Coumaphos (cont'd)

Part 158, Subpart C - Product Chemistry Footnotes

1/For the 90% T (EPA Registration No. 11556-11), the following information must be provided: (i) a description of the procedures used to assure consistent composition of the substance produced (quality control methods); (ii) the name and address of the producer of each starting material and information concerning its composition; (iii) a flow chart of the chemical equations of each intended reaction occurring at each step of the process and of the entire process; and (iv) a description of any purification procedures (including procedures to recycle starting materials, intermediates or the substance produced).

2/For the Bayvet 90% T (EPA Registration No. 11556-11), a discussion regarding the origin of the following potential impurities must be provided: the possible degradation of ingredients in the product after production, postproduction reactions between the ingredients in the product, possible contamination from packaging materials or production equipment, and process control, purification, and quality control measures.

3/Five or more representative samples must be analyzed for the amount of active ingredient and each impurity present at 0.1% or greater. If the product is produced by a batch process, five separate batches should be represented in preliminary analyses. Complete and detailed descriptions of the methods used for sample analysis must be submitted, including statements of their precision and accuracy. The preliminary analysis report should include the identity and quantity of each ingredient for which analysis is conducted along with the mean and relative standard deviation of the analytical results. Based on the preliminary analysis, a statement of the composition of the technical grade and active ingredient must be provided.

4/As required by 40 CFR 158.190 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, Guidelines Reference Nos. 63-2 through 63-13, data must be submitted on physicochemical characteristics (dissociation constant, octanol/water partition coefficient, and stability). There are additional data requirements listed in Table B pertaining to physicochemical characteristics of those technical products which are also manufacturing-use products.

5/Data on octanol/water partition coefficient are required if the technical chemical is organic and nonpolar.

6/If samples are needed, the Agency will request them.

Table A
Generic Data Requirements for Coumaphos

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
158.240 - Residue Chemistry					
171-4 - Nature of the Residue (Metabolism)-Plants	PAIRA and Plant Metabolites	N/A			
171-4 - Nature of the Residue (Metabolism)-Animals	PAIRA and Plant Metabolites	Partially	00005392,00005402, 00005450,00005454, 05004087,05004483, 05012748	Yes[1]/	1 Year
171-4 - Residue Analytical Methods	TGAI and Metabolites	Partially	00005195,00005289, 00005342,00005438	Yes[2]/	1 Year
171-4 - Storage Stability Data	TEP and Metabolites	Partially	00005341,00073248	Yes[3]/	1 Year
171-4 - Magnitude of Residue in Plants		N/A			

Table A
Generic Data Requirements for Coumaphos (cont'd)

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
158.240 - Residue Chemistry					
171-4 - Magnitude of Residue in Meat and Milk	TGAI and Plant Metabolites	Partially	00005042,00005047, 00005048,00005051, 00005056,00005074, 00005080,00005081, 00005082,00005235, 00005293,00005295, 00005330,00005331, 00005333,00005339, 00005393,00005399, 00005400,00005441, 00005447,00005448, 00005451,00005453, 00005456,00005479, 00005480,00005483, 00005485,00005489, 00005493,00005510, 00005822,00005830, 00005832,00005833, 00005834,00021731, 00021732,00060807	Reserved[4/]	

Table A
Generic Data Requirements for Coumaphos (cont'd)

Sec. 158.240 Residue Chemistry Footnotes

1/Metabolism studies, conducted using [^{14}C]-benzene-ring labeled coumaphos and characterizing total terminal residue of coumaphos in ruminants are required. Animals must be dosed dermally with [^{14}C]-benzene-ring labeled coumaphos at levels sufficient to make residue identification and quantification possible. Milk must be collected twice a day during the dosing period, and test animals must be sacrificed within 24 hours of the final dose. The distribution and identities of residues must be determined in milk, liver, kidney (ruminants only), muscle, and fat. Representative samples from the required metabolism studies must also be analyzed using a suitable confirmatory method such as MS or HPLC, and using accepted enforcement methods to ascertain that these methods will recover and quantify all metabolites of concern. Should the metabolism of coumaphos in ruminants and/or poultry differ significantly from that in rats, swine metabolism data may also be required.

2/Representative animal tissue samples bearing residues of coumaphos and its oxygen analog must be subjected to multiresidue protocol III from PAM Vol. I, Appendix II. Multiresidue protocols I to IV are available from the National Technical Information Service under Order No. PB 203734/AS. The nature of the residues in animals is not understood. If the metabolism studies requested in the section "Qualitative Nature of the Residue in Animals" reveal the presence of additional metabolites of concern, additional validated methods for data collection and tolerance enforcement will be required.

3/The sample storage conditions and intervals must be supplied for all required and previously submitted residue data for animal commodities. Storage stability data in support of previously submitted residue data are required for only those samples deemed to be useful for tolerance assessment. Data are also required which depict the decline in levels of coumaphos residues of concern in commodities stored under the range of conditions and for the range in intervals specified. Fortified meat samples must be analyzed immediately after harvest or fortification and again after storage intervals that represent actual residue sample storage conditions and allow for reasonable unforeseen delays in sample analysis. In laboratory tests using fortified samples, the pure active ingredient and pure metabolites must be used. For additional guidance on conducting storage stability studies, the registrant is referred to an August 1987 Position Document on the Effects of Storage on Validity of Pesticide Residue Data available from NTIS under Order No. PB 88112362/AS.

4/The qualitative nature of the residue in animals is not adequately understood; therefore, the adequacy of the available data pertaining to residues of coumaphos and its oxygen analog in meat and milk cannot be ascertained. On receipt of the requested metabolism data, the adequacy of the established tolerances will be determined. If these studies reveal the existence of additional residues of toxicological concern, additional data may be required.

Table A
Generic Data Requirements for Coumaphos

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submissio
158.290 - Environmental Fate						
Degradation Studies - Lab						
161-1 - Hydrolysis	TGAI or PAIRA	I	No		Yes[1]/	1 Year
Photodegradation						
161-2 - In Water	TGAI or PAIRA	I	No		Yes[2]/	1 Year
161-3 - On Soil	TGAI or PAIRA	I	No		Yes[2]/	1 Year
161-4 - In Air	TGAI or PAIRA	N/A				
METABOLISM STUDIES - LAB:						
162-1 - Aerobic Soil	TGAI or PAIRA	N/A	No		No[3]/	
162-2 - Anaerobic Soil	TGAI or PAIRA	N/A				
162-3 - Anaerobic Aquatic	TGAI or PAIRA	N/A				
162-4 - Aerobic Aquatic	TGAI or PAIRA	N/A				

Table A
Generic Data Requirements for Coumaphos (cont'd)

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
158.290 - Environmental Fate (cont'd)						
MOBILITY STUDIES:						
163-1 - Leaching and Adsorption/ Desorption	TGAI or PAIRA	I	Partially	00163806	Yes[4]	2 Years
163-2 - Volatility (Lab)	TEP	N/A				
163-3 - Volatility (Field)	TEP	N/A				
DISSIPATION STUDIES - FIELD:						
164-1 - Soil	TEP	N/A	No		No[5]	
164-2 - Aquatic (Sediment)	TEP	N/A				
164-3 - Forestry	TEP	N/A				
164-4 - Combination and Tank Mixes	TEP	N/A				
164-5 - Soil, Long-Term	TEP	N/A				
ACCUMULATION STUDIES:						
165-1 - Rotational Crops (Confined)	PAIRA	N/A				
165-2 - Rotational Crops (Field)	TEP	N/A				

Table A
Generic Data Requirements for Coumaphos (cont'd)

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
158.290 Environmental Fate (cont'd) ACCUMULATION STUDIES: (cont'd)						
165-3 - Irrigated Crops	TEP	N/A				
165-4 - In Fish	TGAI or PAIRA	N/A	No		No[6]	
165-5 In Nontarget Organisms	TEP	N/A				
158.440 Spray Drift						
201-1 Droplet Size Spectrum	TEP	N/A				
201-1 Drift Field Evaluation	TEP	N/A				
158.75 - Other						
Groundwater Monitoring	TEP	I	No		Yes[7]	

Table A
Generic Data Requirements for Coumaphos (cont'd)

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
158.140 - Reentry Protection						
132-1 - Foliar Dissipation	TEP	N/A				
132-1 - Soil Dissipation	TEP	N/A				
133-3 - Dermal Exposure	TEP	N/A				
133-4 - Inhalation Exposure	TEP	N/A				
40 CFR 158.75 Applicator Exposure Monitoring						
231 - Estimation of Dermal Exposure						
- Indoor Site	TEP	I	No		Reserved[8]	
232 - Estimation of Inhalation Exposure						
- Indoor Site	TEP	I	No		Reserved[8]	
233 - Estimation of Dermal Exposure						
- Indoor Site	TEP	I	No		Reserved[8]	

Table A
Generic Data Requirements for Coumaphos (cont'd)

Sec. 158.290 and 158.390 Environmental Fate Footnotes

1/The 1981 Standard required submission of a hydrolysis study. This study was reviewed and found to be inadequate due to design and reporting flaws. Normally no study is required because of coumaphos's general indoor use pattern (CFR 40 Part 158.290, App. A, Use Pattern Index). However, because point source contamination might arise at animal treatment sites, this study is required in order to evaluate the potential of coumaphos to impact on ground or surface water.

2/Normally no study is required because of coumaphos's general indoor use pattern (CFR 40 Part 158.290, App. A, Use PatternIndex). However, because point source contamination might arise at animal treatment sites, this study is required in order to evaluate the potential of coumaphos to impact on ground or surface water. Due to recurring problems that other registrants have encountered in interpreting this guideline, the registrant for coumaphos should submit a protocol before initiating the two studies. Among the issues that the registrant should be advised of are the following: 1) in a soil photodegradation study where microbial degradation is significant (i.e., on soil), continuous (24 hour) exposure to an artificial light source will invalidate the results; 2) a comparison must be made between any artificial light source and natural light (in terms of intensity, spectral distribution, and exposure time).

3/The 1981 Coumaphos Registration Standard required submission of an aerobic soil metabolism study. The study submitted (MRID 4018701) was reviewed and found to be inadequate due to design and reporting flaws. However, the Agency has determined that this study is not needed to support coumaphos's indoor use pattern.

4/Normally no study is required because of coumaphos's general indoor use pattern (40 CFR Part 158.290, App. A. Use Pattern Index). However, because point source contamination might arise at animal treatment sites, this study is required in order to evaluate the potential of coumaphos to impact on ground or surface water. This study must be conducted according to the guideline for a batch equilibrium adsorption/desorption study using the parent and two major degradates, chloroferone and HOL 5461, as test substances.

5/A study submitted (MRID 00115166) was reviewed and determined to be unacceptable due to design and reporting flaws. This study is not required to support the presently registered use.

Table A
Generic Data Requirements for Coumaphos (cont'd)

Sec. 158.290 and 158.390 Environmental Fate Footnotes
cont'd

6/The 1981 Coumaphos Registration Standard required submission of a fish accumulation study. The study submitted (MRID 00115168, 00150619) was reviewed and found to be inadequate due to design and reporting flaws. However, the Agency has determined that this study is not needed to support coumaphos's indoor use pattern.

7/Because point source contamination might arise at animal treatment sites, this study is required in order to evaluate the potential of coumaphos to impact on ground or surface water. This study is intended as a retrospective study to assess the dissipation of coumaphos under typical use conditions.
The protocol for this field study should be designed to retrospectively evaluate the dissipation of coumaphos at a minimum six major use areas in the continental United States including at least one site involving a sandy soil over a shallow water table. The study should also include analysis of water samples from nearby existing wells. Core samples from these use sites must be measured to a depth to fully define the extent of leaching of the parent and major degradates.
Prior to initiating this special study, the registrant should conduct a briefing for the staff of EFGWB discussing the actual use practices for application and disposal of coumaphos, the sites proposed for retrospective investigation and provide a draft protocol for branch review. Further testing is reserved pending results of the retrospective study.

8/The Agency will evaluate occupational and nonoccupational exposure data requirements upon submission and review of the toxicology data.

Table A
Generic Data Requirements for Coumaphos

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
158.340 - Toxicology						
ACUTE TESTING						
81-1 - Acute Oral - Rat	TGAI	I	Yes	00110597	No	
81-2 - Acute Dermal - Rat	TGAI	I	Yes	00110598	No	
81-3 - Acute Inhalation						
- Rat	TGAI	I	Yes	00110601	No	
81-4 - Eye Irritation						
- Rabbit	TGAI	I	Yes	00110599	No	
81-5 - Dermal Irritation						
- Rabbit	TGAI	I	Yes	00110600	No	
81-6 - Dermal Sensitization						
- Guinea Pig	TGAI	I	Yes	00110602	No	
81-7 - Acute Delayed Neurotoxicity						
- Hen	TGAI	I	Yes	00115167	No	

Table A
Generic Data Requirements for Coumaphos (cont'd)

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
158.340 - Toxicology (cont'd)						
SUBCHRONIC TESTING						
82-1 - 90-Day Feeding						
- Rodent	TGAI	I	No		No[1/]	
- Nonrodent	TGAI	I	No		No[2/]	
82-2 - 21-Day Dermal	TGAI	I	No		Yes[3/]	1 Year
82-3 - 90-Day Dermal	TGAI	I	N/A			
82-4 - 90-Day Inhalation	TGAI	I	N/A			
82-5 - 90-Day Neurotoxicity	TGAI	I	N/A			
83-1 - Chronic Testing						
- Rodent	TGAI	I	Yes	40836001	No	
- Nonrodent	TGAI	I	No		Yes[4/]	4 Years (12 Months - Progress Report - Semiannually thereafter)

Table A
Generic Data Requirements for Coumaphos (cont'd)

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
158.340 - Toxicology (cont'd)						
SUBCHRONIC TESTING (cont'd)						
83-2 - Oncogenicity						
- Rat	TGAI	I	Yes	40836001,05009938	No	
- Mouse	TGAI	I	Yes	05009938	No	
CHRONIC TESTING						
83-3 - Teratogenicity						
- Rat	TGAI	I	Yes	00131684	No	
- Mouse	TGAI	I	Yes	00131683	No	
83-4 - Reproduction						
- 3-Generation	TGAI	I	No		Yes[5]	4 Years (12 Months - Progress Report; Semiannually thereafter)

Table A
Generic Data Requirements for Coumaphos (cont'd)

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
158.340 - Toxicology (cont'd)						
MUTAGENICITY TESTING						
84-2 - Gene Mutation	TGAI	I	Yes	00131680	No	
84-2 - Chromosome Aberration	TGAI	I	No		Yes[6]	1 Year
84-4 - Other Mechanisms of of Mutagenicity	TGAI	I	Yes	00131681	No	
SPECIAL TESTING						
85-1 - General Metabolism	PAI or PAIRA	I	Yes	01155611	No	
85-2 - Domestic Animal Safety	Choice	I	Yes	00138251	No[7]	

1/This study is not required since an adequate chronic toxicity/oncogenicity study in rats has been submitted.
2/A chronic feeding study in dogs is required and supercedes the requirement for a 90-day feeding study.
3This study is required since the use of coumaphos (especially with dust bag applications when charging and recharging the bags) may result in dermal contact.
4/The Agency overlooked the requirement for a dog chronic toxicity study in the 1981 standard.
5/Although this requirement was waived in 1984, the Agency now believes a reproduction study is needed in order to provide information on the effects of the test substance on the gonadal function, estrous cycles, mating behavior, conception, parturition, lactation, weaning, and growth and development of the offspring.
6/The micronucleus study (MRID 00131682) is no longer considered valid since the test substance did not induce toxic effects in mice and only one dose level was tested.
7/Domestic animal safety testing on horses; used to support the 42% flowable concentrate (EPA reg. No. 11556-98).

Table A
Generic Data Requirements for Coumaphos

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
158.490 - Wildlife and Aquatic Organisms						
AVIAN AND MAMMALIAN TESTING						
71-1 - Avian Oral LD_{50}	TGAI	I	Yes	00160000	No	
71-2 - Avian Dietary LC_{50}						
a. Waterfowl	TGAI	I	Yes	00022923	No	
b. Upland Game Bird	TGAI		Yes	00022923	No	
71-3 - Wild Mammal Toxicity	TGAI	N/A				
71-4 - Avian Reproduction						
a. Waterfowl	TGAI	N/A				
b. Upland Game Bird	TGAI	N/A				
71-5 - Simulated or Field Testing Birds and Mammals	TEP	I	No		Yes1/	3 Years (Acceptable Protocol- 90 Days)

Table A
Generic Data Requirements for Coumaphos (cont'd)

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
158.490 - Wildlife and Aquatic Organisms (cont'd)						
AQUATIC ORGANISM TESTING						
72-1 - Acute Toxicity Freshwater						
a. Warmwater	TGAI	I	Yes	40098001	No	
	TEP	N/A				
b. Coldwater	TGAI	I	Yes	40098001	No	
	TEP	N/A				
72-2 - Acute LC_{50} Freshwater Invertebrates	TGAI		Yes	05009242	No	
	TEP	N/A				
72-3 - Acute LC_{50} Estuarine						
- Fish	TGAI	N/A				
	TEP					
- Shrimp	TGAI	N/A				
	TEP	N/A				
- Mollusk	TGAI	N/A				
	TEP	N/A				
72-4 - Fish Early Life Stage	TGAI	N/A				
72-4 - Aquatic Invertebrate Life Cycle	TGAI	N/A				

Table A
Generic Data Requirements for Coumaphos (cont'd)

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
158.490 - Wildlife and Aquatic Organisms (cont'd)						
72-5 - Fish Full Life Cycle	TGAI	N/A				
72-6 - Aquatic Organism		N/A				
72-7 - Simulated or Actual Field Testing Aquatic Organisms	TEP	N/A				
Special Testing Requirements						
70-1 Monitoring - Aquatic Invertebrates and Residues	TEP	I	No		Yes[2]	3 Years (Acceptable Protocol-90 Days)

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[1] Field testing for avian effects is required to support the livestock use. This testing involves multiple field (>8) treatment and searching for dead birds. For design guidance, see Terrestrial Field Studies Guidance Document (Fite, et. al. 1988). The registrant must submit a protocol within 90 days and complete the testing and submit a final report within three years. The livestock must be treated with 0.04 lb a.i./100 lb. At least 100 head of cattle must be treated at each of the eight sites. Sites must be chosen where a large number of birds regularly feed on and annoy treated cattle. Samples of hair and insects from the backs of cattle should be monitored.

[2] Monitoring of aquatic invertebrate mortality and residues must be conducted for the direct animal treatment use on livestock.

Table A
Generic Data Requirements for Coumaphos

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
158.540 - Plant Protection Testing						
NONTARGET AREA PHYTOTOXICITY						
TIER I						
122-1 - Seed Germination/Seedling Emergence	TGAI	N/A				
122-1 - Vegetative Vigor	TGAI	N/A				
122-2 - Aquatic Plant Growth						
- Algae Testing	TGAI	N/A				
- Vascular Plants	TGAI	N/A				
TIER II						
123-1 - Seed Germination/Seedling Emergence	TGAI	N/A				
123-2 - Aquatic Plant Growth						
- Algae Testing	TGAI	N/A				
- Vascular Plants	TGAI	N/A				
TIER III						
124-2 - Terrestrial and Aquatic Field Studies	TEP	N/A				

Table A
Generic Data Requirements for Coumaphos

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
158.590 - Nontarget Insects						
NONTARGET INSECT TESTING - POLLINATORS						
141-1 - Honey Bee Acute Toxicity	TGAI	N/A				
141-2 - Honey Bee - Toxicity of Residues on Foliage	TEP	N/A				
141-4 - Honey Bee Subacute Feeding Study	TEP	N/A				
141-5 - Field Testing for Pollinators	TEP	N/A				
NONTARGET INSECT TESTING - AQUATIC INSECTS						
142-1 - Acute Toxicity to Aquatic Insects		N/A				
142-2 - Aquatic Insect Life Cycle Study		N/A				
142-3 - Simulated or Actual Field Testing for Aquatic Insects		N/A				
NONTARGET INSECT TESTING - PREDATORS AND PARASITES						
143-1 thru 143-3		N/A				

Table B
Product-Specific Data Requirements for Manufacturing-Use Products Containing Coumaphos

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
Part 158, Subpart C - Product Chemistry					
Product Identity and Composition					
61-1 - Product Composition	MP	Partially	00110596	Yes[1]/	1 Year
61-2 - Beginning Materials and Production or Formulation Process	MP	Partially	00110596	Yes[2]/	1 Year
61-3 - Discussion of Formation of Impurities	MP	Partially	00110596	Yes[3]/	1 Year
Analysis and Certification of Product Ingredients					
62-1 - Preliminary Analysis	MP	Partially	00110596	Yes[4]/	2 Years
62-2 - Certified Limits	MP	Partially	00110596	Yes[5]/	2 Years
62-3 - Enforcement Analytical Methods	MP	Yes	00110596	Yes[6]/	2 Years
Physical and Chemical Characteristics					
63-2 - Color	MP	Yes	00110596	No	
63-3 - Physical State	MP	Yes	00110596	No	

Table B
Product-Specific Data Requirements for Manufacturing-Use Products Containing Coumaphos (cont'd)

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
Part 158, Subpart C - Product Chemistry (cont'd)					
Physical and Chemical Characteristics					
62-4 - Odor	MP	Yes	00110596,	No	
63-7 - Density, Bulk Density or Specific Gravity	MP	Yes	00110596	No	
63-12 - pH	MP	Yes	00110596	No	
62-14 - Oxidizing or Reducing Action	MP	No		Yes[7,8]/	1 Year
62-15 - Flammability	MP	No		No[9]/	2 Years
63-15 - Explodabilty	MP	No		Yes[7,11]/	1 Year
63-17 - Storage Stability	MP	Partially	00110596,00117974	Yes[7]/	2 Years
63-18 - Viscosity	MP	No		No[10]/	
63-19 - Miscibility	MP	No		No[12]/	
63-20 - Corrosion Characteristics	MP	No		Yes[7]/	2 Years

Table B
Product-Specific Data Requirements for Manufacturing-Use Products Containing Coumaphos (cont'd)

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
Part 158, Subpart C - Product Chemistry (cont'd)					
Analysis and Certification of Product Ingredients (cont'd)					
Other Requirements					
64-1 - Submittal of Samples		No		No[13]	

Table B
Generic Data Requirments for Coumaphos (cont'd)

Part 158, Subpart C - Product Chemistry Footnotes

1/For the Bayvet 90% T (EPA Registration No. 11556-11) certified limits in accordance with section 158.175 and nominal concentrations for the active ingredient and each impurity, and the chemical name of each impurity. For the Bayvet 25% FI (EPA Registration No. 11556-20), the chemical/common name and CAS Registry Number of each inert ingredient in the product.

2/For the 90% T (EPA Registration No. 11556-11), the following information must be provided: (i) a description of the procedures used to assure consistent composition of the substance produced (quality control methods); (ii) the name and address of the producer of each starting material and information concerning its composition; (iii) a flow chart of the chemical equations of each intended reaction occurring at each step of the process and of the entire process; and (iv) a description of any purification procedures (including procedures to recycle starting materials, intermediates or the substance produced). For the 25% FI the following information must be provided: (i) the name and EPA Registration Number of the EPA-registered product and information concerning the identity of each inert ingredient; (ii) a description of the conditions (e.g., temperature, pressure, pH, humidity) that are controlled during each step of the process; and (iii) a description of the procedures used to assure consistent composition of the substance produced (quality control methods).

3/For the Bayvet 90% T (EPA Registration No. 11556-11), a discussion regarding the origin of the following potential impurities must be provided: the possible degradation of ingredients in the product after production, postproduction reactions between the ingredients in the product, possible contamination from packaging materials or production equipment, and process control, purification, and quality control measures. For the Bayvet 25% FI (EPA Registration No. 11556-20), a discussion must be provided for each impurity associated with the active ingredient which the registrant has reason to believe may be present in the product at a level equal to or greater than 0.1% (w/w) based on the possible carryover of impurities present in the registered product which serves as the source of the active ingredient, the possible carryover of impurities present in the inert ingredients in the product, possible reactions occurring during the formulation of the product, postproduction reactions between any of the product's active ingredients and any other component of the product or its packaging, and possible contamination from packaging materials or production equipment.

4/For each manufacturing-use product produced by an integrated system, the registrant must provide preliminary analyses of five or more representative samples of the each technical grade of the active ingredient (TGAI) contained in the product to identify all impurities present at 0.1% or greater of the TGAI. If the product is produced by a batch process, at least five separate batches should be represented. The preliminary analysis should be conducted at the point in the production process after which no further chemical reactions designed to produce or purify the substance are intended. Complete and detailed descriptions of the methods used for sample analysis must be submitted, including a statement of their precision and accuracy. The preliminary analysis 1

Table B
Generic Data Requirments for Coumaphos (cont'd)

Part 158. Subpart C - Product Chemistry Footnotes (cont'd)

report should include the identity and quantity of each ingredient for which analysis is conducted, along with the mean and relative standard deviation of the analytical results. Based on the preliminary analysis, a statement of the composition of the TGAI must be provided.

5/For the Bayvet 90% T (EPA Registration No. 11556-11) the registrant must provide an explanation as to how the proposed upper and lower certified limits for the active inert ingredient were established (e.g., sample analysis using a validated analytical procedure, quantitative estimate based on the amounts of ingredients used, etc.), since these limits differ from the standard certified limits determined by the Agency according to 40 CFR 158.175(b)(2). For the 25% FI (EPA Registration No. 11556-20) the registrant must submit a statement of agreement that the certified limits of the ingredients will be maintained. The registrant must propose certified limits for ingredients in the 25% FI if those limits would differ from those determined in accordance with 40 CFR 158.175(b)(2). Information on the accuracy and precision of any analytical procedures used must also be provided. In addition, certifications must be submitted on EPA Form 8570-4 (Rev. 2/85).

6/Analytical methods which are suitable for enforcement purposes must be provided for each active ingredient and each other ingredient or impurity that is determined to be toxicologically significant. Suitability of submitted methods for enforcement purposes shall be determined from statements of method accuracy and precision which must be provided for the analytical methods submitted by Bayvet Corporation and described in MRID No. 00110596.

7/As required in 40 CFR 158.190 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, Guidelines Reference Nos. 63-2 through 63-20, data must be submitted on physicochemical characteristics of each manufacturing-use product (oxidizing or reducing action, explodability, storage stability, and corrosion characteristics). Additional data requirements regarding physicochemical properties of manufacturing-use products which contain only the TGAI are listed in Table A, "Generic Data Requirements for the Coumaphos Technical Grade of the Active Ingredient."

8/Data are required on oxidizing/reducing potential if the product contains an oxidizing or reducing agent.

9/Data are not required on flammability since the products do not contain combustible liquids.

10/Data on viscosity are not required since the products are not liquids.

11/Data are required if the product is potentially explosive.

12/Data on miscibility are not required since the products are not emulsifiable liquids to be diluted with petroleum solvents.

13/If samples are needed, the Agency will request them.

Table B
Product-Specific Data Requirements for Manufacturing-Use Products Containing Coumaphos

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
158.340 - Toxicology					
ACUTE TESTING					
81-1 - Oral - Rat	MP[1]	Yes	00110597	No	
81-2 - Dermal	MP	Yes	00110598	No	
81-3 - Inhalation - Rat	MP	Yes	00110601	No	
81-4 - Primary Eye Irritation					
- Rabbit	MP	Yes	00110599	No	
81-5 - Primary Dermal Irritation	MP	Yes	00110600	No	
81-6 - Dermal Sensitization	MP	Yes	00110602	No	

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[1] Formulation intermediates are included in the category of manufacturing-use products.

Table C
Product Specific Data Requirements for End-Use Products Containing Coumaphos (25% WP)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission-
Sec. 158.340 Toxicology						
Acute Testing						
81-1 - Acute Oral - Rat	TEP	I	Yes	00110603	No	
81-2 - Acute Dermal Toxicity - Rabbit	TEP	I	Yes	00110604	No	
81-3 - Acute Inhalation Toxicity - Rat	TEP	I	Yes	00110607	No	
81-4 - Primary Eye Irritation - Rabbit	TEP	I	Yes	00110605	No	
81-5 - Primary Dermal Irritation - Rabbit	TEP	I	Yes	00110606	No	
81-6 - Dermal Sensitization-Guinea Pig	TEP	I	Yes	00110608	No	

Table C
Product Specific Data Requirements for End-Use Products Containing Coumaphos (11.6% EC)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission-
Sec. 158.340 Toxicology						
Acute Testing						
81-1 - Acute Oral - Rat	TEP	I	Yes	00112832	No	
81-2 - Acute Dermal Toxicity - Rabbit	TEP	I	Yes	00112833	No	
81-3 - Acute Inhalation Toxicity - Rat	TEP	I	Yes	00112836	No	
81-4 - Primary Eye Irritation - Rabbit	TEP	I	Yes	00112834	No	
81-5 - Primary Dermal Irritation - Rabbit	TEP	I	Yes	00112835	No	
81-6 - Dermal Sensitization-Guinea Pig	TEP	I	Yes	00112837	No	

Table C
Product Specific Data Requirements for End-Use Products Containing Coumaphos (0.5%, 1% and 5% D)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission-
Sec. 158.340 Toxicology						
Acute Testing						
81-1 - Acute Oral - Rat	TEP	I	Yes	00110609	No	
81-2 - Acute Dermal Toxicity - Rabbit	TEP	I	Yes	00112816	No	
81-3 - Acute Inhalation Toxicity - Rat	TEP	I	Yes	00112820	No	
81-4 - Primary Eye Irritation - Rabbit	TEP	I	Yes	00112818	No	
81-5 - Primary Dermal Irritation - Rabbit	TEP	I	Yes	00112817	No	
81-6 - Dermal Sensitization-Guinea Pig	TEP	I	Yes	00112819	No	

NOTE: Data are not available for the 0.5% and 5% dust formulations. The toxicity categories assigned to the 0.5% and 5% formulations are based upon data generated for the 1% formulation. If the registrant wishes to challenge the classification of the 0.5% or 5% formulations, acute oral and inhalation studies must be submitted.

Table C
Product Specific Data Requirements for End-Use Products Containing Coumaphos (3% Spray)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission-
Sec. 158.340 Toxicology						
Acute Testing						
81-1 - Acute Oral - Rat	TEP	I	Yes	00112821	No	
81-2 - Acute Dermal Toxicity - Rabbit	TEP	I	Yes	00112822	No	
81-3 - Acute Inhalation Toxicity - Rat	TEP	I	Yes	00112825	No	
81-4 - Primary Eye Irritation - Rabbit	TEP	I	Yes	00112824	No	
81-5 - Primary Dermal Irritation - Rabbit	TEP	I	Yes	00112823	No	
81-6 - Dermal Sensitization- Guinea Pig	TEP	I	Yes	00112826	No	

Table C
Product Specific Data Requirements for End-Use Products Containing Coumaphos (4% Pour-On)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission-
Sec. 158.340 Toxicology						
Acute Testing						
81-1 - Acute Oral - Rat	TEP	I	Yes	00112827	No	
81-2 - Acute Dermal Toxicity - Rabbit	TEP	I	Yes	00112827	No	
81-3 - Acute Inhalation Toxicity - Rat	TEP	I	Yes	00112830	No	
81-4 - Primary Eye Irritation - Rabbit	TEP	I	Yes	00112828	No	
81-5 - Primary Dermal Irritation - Rabbit	TEP	I	Yes	00112829	No	
81-6 - Dermal Sensitization- Guinea Pig	TEP	I	Yes	00112831	No	

Table C
Product Specific Data Requirements for End-Use Products Containing Coumaphos (42% Flowable)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission-
Sec. 158.340 Toxicology						
Acute Testing						
81-1 - Acute Oral - Rat	TEP	I	Yes	00026376,00026377 00026379,00026371	No	
81-2 - Acute Dermal Toxicity - Rabbit	TEP	I	Yes	00026375,00026378 00026372	No	
81-3 - Acute Inhalation Toxicity - Rat	TEP	I	Yes	00026374	No	
81-4 - Primary Eye Irritation - Rabbit	TEP	I	Yes	00026370	No	
81-5 - Primary Dermal Irritation - Rabbit	TEP	I	Yes	00026373	No	
81-6 - Dermal Sensitization-Guinea Pig	TEP	I	Yes	00082524	No	
82-2 - 21-Day Dermal Toxicity	TEP	I	Yes	00117106	No	

Table C
Product-Specific Data Requirements for End-Use Products Containing Coumaphos

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data/ Submission
Part 158, Subpart C - Product Chemistry					
Product Identity and Composition					
61-1 - Product Identity and Yes 1 Year Disclosure of Ingredients	EP	Yes	00110596	No	
61-2 - Description of Beginning Materials and Manufacturing Process	EP	Yes	00110596	No	
61-3 - Discussion of Formation of Impurities	EP	Yes	00110596	No	
Analysis and Certification of Product Ingredients					
62-1 - Preliminary Analysis of Product Samples	EP	Yes	00110596	No	
62-2 - Certification of Ingredient Limits	EP	Yes	00110596	No	
62-3 - Analytical Methods to Verify Certified Limits	EP	Yes	00110596	No	

Table C
Product-Specific Data Requirements for End-Use Products Containing Coumaphos (cont'd)

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
Part 158, Subpart C - Product Chemistry					
Physical and Chemical Characteristics (cont'd)					
Physical and Chemical Characteristics					
63-2 - Color	EP	Yes	00110596	No	
63-3 - Physical State	EP	Yes	00110596	No	
63-4 - Odor	EP	Yes	00110596	No	
63-7 - Density, Bulk Density, or Specific Gravity	EP	Yes	00110596	No	
63-12 - pH	EP	Yes	00110596	No	
62-14 - Oxidizing or Reducing Action	EP	Yes	00110596	No	
62-15 - Flammability	EP	Yes	00110596	No	
63-16 - Explodability	EP	Yes	00110596	No	
63-17 - Storage Stability	EP	Yes	00110596,00117974	No	
63-18 - Viscosity	EP	Yes	00110596	No	
63-19 - Miscibility	EP	Yes	00110596	No	

Table C
Product-Specific Data Requirements for End-Use Products Containing Coumaphos (cont'd)

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Datal/ Submission
Part 158, Subpart C - Product Chemistry					
Physical and Chemical Characteristics (cont'd)					
63-20 - Corrosion Characteristics	EP	Yes	00110596	No	
Other Requirements					
64-1 - Submittal of Samples	N/A				

NOTE: Data contained in MRID 00110596 satisfies product-specific data requirements for end-use formulations containing 3% spray, 4% pour-on, 11.6% EC, 42% flowable, 0.5% D, 1% D, 5% D, and 25% WP.

II. LABELING APPENDICES

SUMMARY-1

LABEL CONTENTS

40 CFR 156.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label test. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 156.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 156.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 156.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 156.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely.
[40 CFR 156.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement.
[40CFR 156.10(h)(1)(i)].

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON.
[40 CFR 156.10(h)(1)(i)].

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 156.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "see Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 156.10(h)(1)(iii)].

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 156.10(h)(2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 156.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 156.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

   a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 156.10(h)(1)(iv).

   b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

   a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to sue or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 156.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

SUMMARY-7

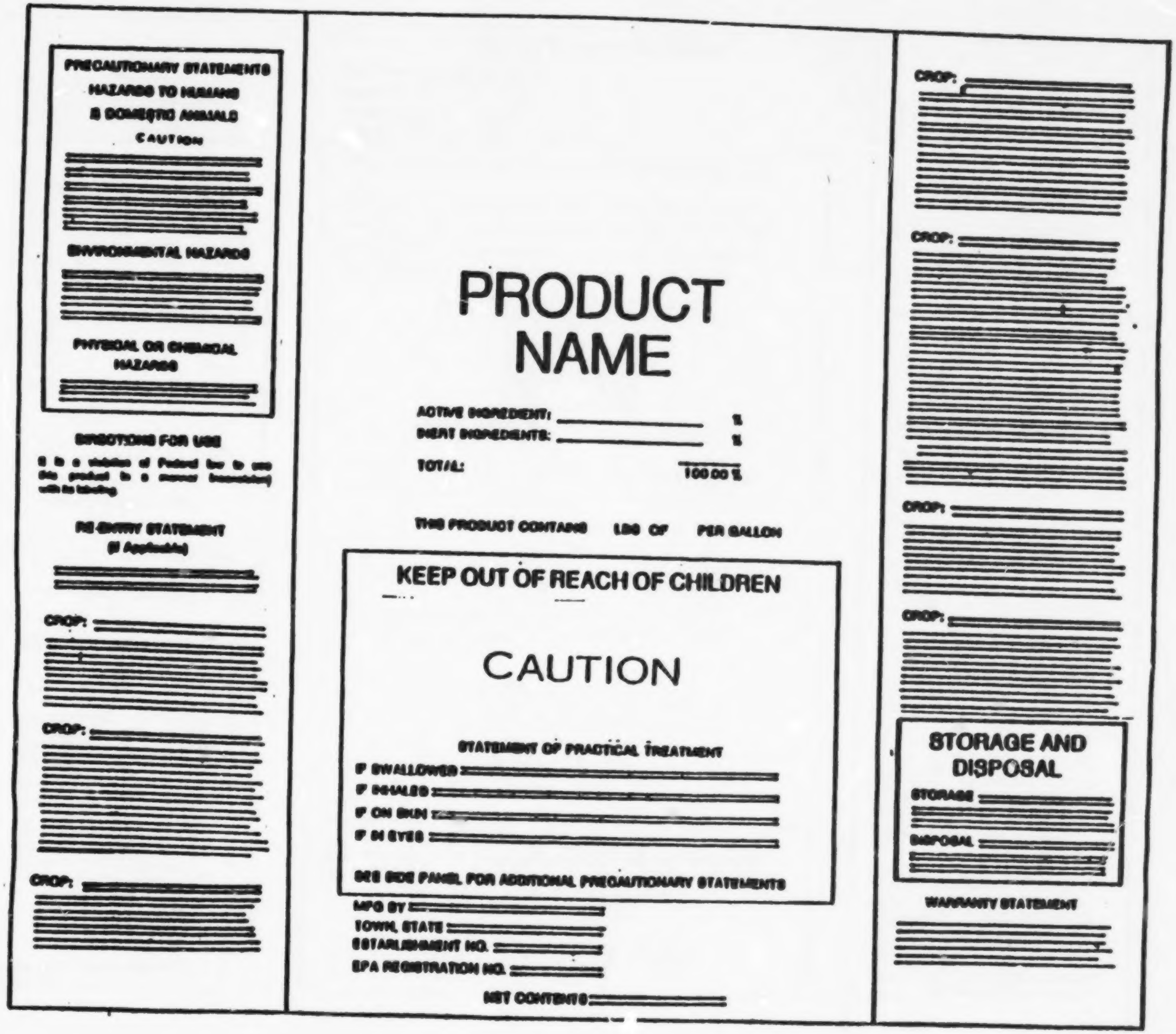
LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

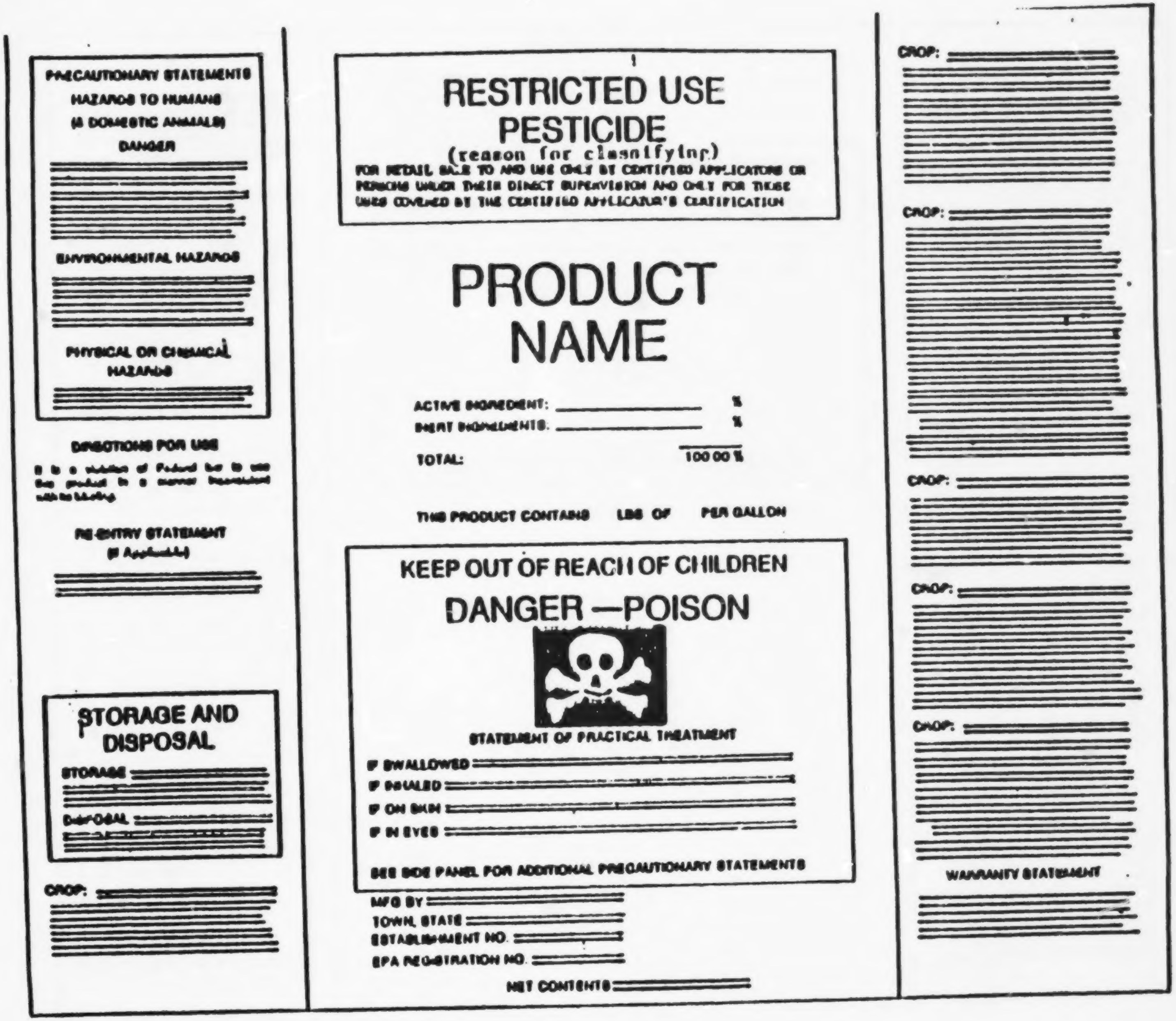
ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL REQUIRED	PLACEMENT ON LABEL PREFERRED	COMMENTS
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . . ," "Distributed by . . . ," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units.
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage is given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

SUMMARY-8

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED (cont'd)

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all	
7E	Referral statement	All products where precautionary labeling appears on other than front panel	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.


PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
& DOMESTIC ANIMALS
CAUTION
ENVIRONMENTAL HAZARDS
PHYSICAL OR CHEMICAL
HAZARDS
DIRECTIONS FOR USE
It is a violation of Federal law to use this product in a manner inconsistent with its labeling
RE-ENTRY STATEMENT
(If Applicable)
CROP:
CROP:
CROP:
PRODUCT
NAME
ACTIVE INGREDIENT: %
INERT INGREDIENTS: %
TOTAL: 100.00 %
THIS PRODUCT CONTAINS LBS OF PER GALLON
KEEP OUT OF REACH OF CHILDREN
CAUTION
STATEMENT OF PRACTICAL TREATMENT
IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES
SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS
MFG BY
TOWN, STATE
ESTABLISHMENT NO.
EPA REGISTRATION NO.
NET CONTENTS
CROP:
CROP:
CROP:
CROP:
STORAGE AND
DISPOSAL
STORAGE
DISPOSAL
WARRANTY STATEMENT



PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
(& DOMESTIC ANIMALS)
DANGER

ENVIRONMENTAL HAZARDS

PHYSICAL OR CHEMICAL HAZARDS

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

RE-ENTRY STATEMENT
(If Applicable)

STORAGE AND DISPOSAL

STORAGE

DISPOSAL

CROP:

RESTRICTED USE PESTICIDE
(reason for classifying)
FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S CERTIFICATION

PRODUCT NAME

ACTIVE INGREDIENT: %
INERT INGREDIENTS: %
TOTAL: 100.00 %

THIS PRODUCT CONTAINS LBS OF PER GALLON

KEEP OUT OF REACH OF CHILDREN

DANGER —POISON

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

MFG BY
TOWN, STATE
ESTABLISHMENT NO.
EPA REGISTRATION NO.

NET CONTENTS

CROP:

CROP:

CROP:

CROP:

CROP:

WARRANTY STATEMENT

156

§ [illegible].10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for

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purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for * * *," "Distributed by * * *," or "Sold by * * *" to show that the name is not that of the producer.

(d) *Net weight or measure of contents.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishments registration number.* The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement*—(1) *General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups: those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) *Required front panel statements.* With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg.	From 50 thru 500 mg/kg	From 500 thru 5000 mg/kg.	Greater than 5000 mg/kg.
Inhalation LC_{50}	Up to and including .2 mg/liter	From .2 thru 2 mg/liter	From 2. thru 20 mg/liter	Greater than 20 mg/liter
Dermal LD_{50}	Up to and including 200 mg/kg.	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000
Eye effects	Corrosive, corneal opacity not reversible within 7 days.	Corneal opacity reversible within 7 days; irritation persisting for 7 days.	No corneal opacity; irritation reversible within 7 days.	No irritation.
Skin effects	Corrosive	Severe irritation at 72 hours.	Moderate irritation at 72 hours.	Mild or slight irritation at 72 hours.

(i) *Human hazard signal word*—(A) *Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) *Child hazard warning.* Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) *Statement of practical treatment*—(A) *Toxicity Category I.* A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.].	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]
III	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV	[No precautionary statements required.]	[No precautionary statements required.]

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20° F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
Flash point above 20° F and not over 80° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20° F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20° F and not over 80° F	Flammable. Keep away from heat and open flame.
Above 80° F and not over 150° F	Do not use or store near heat or open flame.

(i) *Directions for Use*—(1) *General requirements*—(i) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular:" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*—(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(1) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(2) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(3) The product will not come into the hands of the general public except after incorporation into finished products; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(1) The label clearly states that the product is for use only by physicians or veterinarians;

(2) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(3) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(1) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(2) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(3) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning. (See Table in § 162.10(h)(1)(iv))

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j) (1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

PHYSICAL-CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.
2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.
3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.
4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.
5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.
6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

> "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

> "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

> "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording).

[1] Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

III. BIBLIOGRAPHY APPENDICES

Guide to Use of This Bibliography

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

    (1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

    (2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number or other administrative number associated with the earliest known submission.

    (3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARDS BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registrations Under the Coumaphos Standard

MRID	Citation
00005042	Chemagro Corporation (1971) Chemagro Corporation Residue Experiment Nos. AH 70G-810, AH 71G-818: Report No. 30331. (Unpublished study received Oct 29, 1971 under 11556-4; submitted by Bayvet, Shawnee Mission, Kans.; CDL:010122-F)
00005047	Chemagro Corporation (1967) Chemagro Corporation Residue Experiment No. KC-201-66D: Report No. 20652. (Unpublished study received Dec 15, 1967 under 11556-19; submitted by Bayvet, Shawnee Mission, Kans.; CDL:014008-D)
00005048	Chemagro Corporation (1967) Chemagro Corporation Residue Experiment No. KC-300-66H: Report No. 20964. (Unpublished study received Dec 15, 1967 under 11556-19; submitted by Bayvet, Shawnee Mission, Kans.; CDL:014008-E)
00005051	Chemagro Corporation (1968) Chemagro Corporation Residue Experiment No. ?: Report No. 23942. (Unpublished study received Jul 23, 1970 under 11556-16; submitted by Bayvet, Shawnee Mission, Kans.; CDL:007188-A)
00005056	Chemagro Corporation (1963) Chemagro Corporation Residue Experiment No. KC-215-63D: Report No. 12541. (Unpublished study including letter dated Jan 22, 1964 from G.G. Stetson to G.M. Downard, received Jan 28, 1964 under 11556-21; submitted by Bayvet, Shawnee Mission, Kans.; CDL:025715-A)
00005074	Anderson, C.A. (1959) Co-Ral Residues in Goat Tissues: Report No. 4008. (Unpublished study received Sep 11, 1959 under 11556-21; prepared by Chemagro Corp., submitted by Bayvet, Shawnee Mission, Kans.; CDL:011001-A)
00005080	Chemagro Corporation (1969) Synopsis of Analytical and Residue Information for Spray Application of Co-Ral to Dairy Cattle. Summary of studies 006078-B through 006078-G. (Unpublished study received Feb 20, 1970 under 11556-21; submitted by Bayvet, Shawnee Mission, Kans.; CDL:006078-A)
00005081	Chemagro Corporation (1969) Chemagro Corporation Residue Experiment No. KC-201-68D: Report No. 24216. (Unpublished study received Feb 20, 1970 under 11556-21; submitted by Bayvet, Shawnee Mission, Kans.; CDL:006078-G)

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00005082	Industrial Bio-Test Laboratories (1974) Chemagro Division of Baychem Corporation Residue Experiment: AH-74A-929: Report No. 40709. (Unpublished study received Jun 20, 1974 under 11556-21; prepared for Baychem Corp., submitted by Bayvet, Shawnee Mission, Kans.; CDL:009815-A)
00005193	Chemagro Corporation (1957) Co-Ral (Formerly Bayer 21/199) for Experimental Use Only. (Unpublished study received Jul 1, 1957 under unknown admin. no.; submitted by Bayvet, Shawnee Mission, Kans.; CDL:124847-A)
00005195	Anderson, C.A. (1958) A Photofluorometric Method for the Determination of Co-Ral (Bayer 21/199) Residues in Animal Tissues: Report No. 2216. Method dated Aug 13, 1958. (Unpublished study received Feb 27, 1976 under 11556-EX-3; prepared by Chemagro Corp., submitted by Bayvet, Shawnee Mission, Kans.; CDL: 224167-E)
00005235	Chemagro Corporation (1964) Chemagro Corporation Residue Experiment No. KC-214-63D: Report No. 12786. (Unpublished study received Jun 8, 1964 under 11556-25; submitted by Bayvet, Shawnee Mission, Kans.; CDL:102326-B)
00005289	Adams, J. (1964) A Quantitative Method for the Determination of Residues of Co-Ral (0-[3-Chloro-4-methyl umbelliferone] 0,0-Diethyl phosphorothioate) and Chlorferron (3-Chloro-4-methyl-7-hydroxycoumarin) in Animal Tissues and Milk: Report No. 13656. Method dated May 6, 1964. (Unpublished study received Aug 18, 1966 under 7F0612; submitted by Chemagro Corp., Kansas City, Mo.; CDL:090796-K)
00005293	Chemagro Corporation (1966) Chemagro Corporation Residue Experiment No. KC-3400-66D: Report No. 17971. (Unpublished study received Aug 18, 1966 under 7F0612; CDL:090796-Q)
00005295	Chemagro Corporation (1966) Chemagro Corporation Residue Experiment No. KC-3401-66H: Report No. 18522. (Unpublished study received Aug 18, 1966 under 7F0612; CDL:090796-S)
00005330	Chemagro Corporation (1963) Chemagro Corporation Residue Experiment No. KC-201-63D: Report No. 10923. (Unpublished study received on unknown date under PP0306; CDL:090321-D)

OFFICE OF PESTICIDE PROGRAMS
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MRID Citation

00005331 Chemagro Corporation (1961?) Synopsis of Analytical and Residue Information on Co-Ral: (Milk). Summary of studies 090321-F through 090321-H. (Unpublished study received Sep 4, 1961 under PP0306; CDL:090321-E)

00005333 Chemagro Corporation (1960) Residue Report: Report No. 5515. (Unpublished study including report nos. 5533 and 5534, received Sep 4, 1961 under PP0306; CDL:090321-H)

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OFFICE OF PESTICIDE PROGRAMS
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IV. FORMS APPENDICES

EPA Form 8580-1

OMB Approval No. 2070-0057
Expires 11/30/89

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET

EPA REGISTRATION NO

PRODUCT NAME

APPLICANT'S NAME

DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

Attach separate page with a list of the data requirements your company agrees to satisfy.

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

Attach list of data requirements

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE

SIGNATURE

DATE

EPA Form 8580-6

OMB Approval No. 2070-0057
Expires 11/30/89

(To qualify, certify ALL four items)

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:

GUIDANCE DOCUMENT DATE

ACTIVE INGREDIENT

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

US Environmental Protection Agency Washington, DC 20460 **EPA** **Product Specific Data Report**	Registration Standard for:	EPA Registration Number	Form Approved OMB #2070-0057 Expires 11-30-89

Registration Guideline No.	Name of Test	Testing not required for my product listed above *(Check below)*	I am complying with Data Requirements by - Citing MR ID No.	I am complying with Data Requirements by - Submitting Data *(Attached)* *(Check below)*	(For EPA Use Only) Accession numbers assigned
Sec. 158.120 Product Chemistry					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion Characteristics				
63-21	Dielectric breakdown voltage				
Sec. 158.135 Toxicology					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Typed Name and Title	Signature	Date

EPA Form 8580-4 (Rev. 5-88) Previous edition is obsolete.

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OMB Approval No. 2070-005
Expiration Date 11/30/89

GENERIC DATA EXEMPTION STATEMENT

EPA Product Registration Number: ____________________

Registrant's Name and Address: ____

____

As an authorized representative of the registrant of the product identified above, I certify that:

(1) I have read and am familiar with the terms of the Notice from EPA dated ______________ concerning a requirement for submission of "generic" data on the active ingredient ________________________ named under FIFRA Section 3(c)(2)(B).

(2) My firm requests that EPA not suspend the registration of our product, despite our lack of intent to submit the generic data in question, on the grounds that the product contains the active ingredient solely as the result of the incorporation into the product of another product which contains that active ingredient, which is registered under FIFRA Section 3, and which is purchased by us from another producer.

(3) An accurate Confidental Statement of Formula (CSF) for the above-identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the subject active ingredient in my firm's product, or

The CSF dated ____________________ on file with EPA is complete, current and accurate and contains the information requested on the current CSF Form 8570-4. The registered source(s) of the above named active ingredient in my product(s) is/are ________________ and their registration number(s) is/are ______________________.

My firm will apply for an amendment to the registration prior to changing the source of the active ingredient in our product.

(4) I understand, and agree on behalf of my firm, that if at any time any portion of this Statement is no longer true, or if my firm fails to comply with the undertakings made in this Statement, my firm's product's registration may be suspended under FIFRA Section 3(c)(2)(B).

(5) I further understand that if my firm is granted a generic data exemption for the product, my firm relies on the efforts of other persons to provide the Agency with the required generic data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Notice's data requirements, the Agency will consider that both they and my firm are not in compliance and will normally initiate proceedings to suspend the registrations of my firm's product(s) and their product(s), unless my firm commits to submit and submits the required data in the specified time frame. I understand that, in such cases, the Agency generally will not grant a time extension for submitting the data.

Registrant's authorized representative: ________________________________
(Signature

Dated: ______________________ ________________________________
(Typed)

EPA Form 8570-27

★U.S. GOVERNMENT PRINTING OFFICE: 1989-617003/00854